# EPA Registration No. 39967-137 Vol. 3

## RISK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | | |
|---|---|---|---|
| PRODUCT REVIEWER: S Gray | | RMB II | TEAM 34 |
| Description of Action: | | EPA File Symbol/Reg No. 71654-6 | |
| Decision No. 365878 | Submission No. 791672 | Fee for Service Action Code: | |
| FQPA Action Code: 332 | Non-FQPA Action Code: | PRIA FEE AMOUNT: | |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | MARCH | 08 | 2006 |
| EPA PIN DATE | MARCH | 10 | 2006 |
| REVIEWER ASSIGNED DATE | MARCH | 13 | 2006 |
| DATE DUE FROM SCIENCE | | | 2006 |
| DATE DUE TO PM | April | 03 | 2006 |
| DATE DUE OUT OF AGENCY | | | |

| Type of Data: | PSB Product Chemistry | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure |
|---|---|---|---|---|---|---|---|

COMMENTS:

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only | |
|---|---|---|
| | Contract No.: 0030 | *ARCTIC SLOPE*/MANAGER |
| | Final Task: Signature [signature] | 1.5 (Total hrs) |
| C | Reviewer's Comments: | |

| DATE FEE PAID: | RESPONSE CODE: 1130 RESPONSE DATE: 4/5/06 |
|---|---|

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 5, 2006

Thomas C. McEntee
Product Registration Manager
E.I. du Pont de Nemours and Company
Dupont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: Virkon® S
EPA Registration No. 71654-6
Application Date: March 8, 2006
EPA Received Date: March 10, 2006

Dear Mr. McEntee:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification**

- Revised Basic Confidential Statement of Formula (see CSF dated 3/9/06)
- Revised Alternate Confidential Statements of Formula (see CSFs dated 3/9/06)

**General Comments**

Based on a review of the materials submitted, the following comments apply:

The notification application is unacceptable for the following reasons:

1. Update the certified limits for [redacted] for the Basic Confidential Statement of Formula. The upper certified limit must be changed from [redacted] and the lower certified limit from [redacted]

| CONCURRENCES | | | | | | | |
|---|---|---|---|---|---|---|---|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | 4-5-06 | | | | | | |

2. Update the certified limits for [redacted] for the Alternate Fragrance Free Confidential Statement of Formula. The upper certified limit must be changed from [redacted] and the lower certified limit from [redacted]

3. Update the certified limits for [redacted] for the Alternate Fragrance Dye Free Confidential Statement of Formula. The upper certified limit must be changed from [redacted] and the lower certified limit from [redacted]

4. Update the certified limits for [redacted] for the Basic Confidential Statement of Formula. The upper certified limit must be changed from [redacted] and the lower certified limit from [redacted]

5. Update the certified limits for sodium chloride for the Alternate Low Dye Confidential Statement of Formula. The upper certified limit must be changed from 1.58% to 1.57% and the lower certified limit from 1.43 to 1.42%.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CONCURRENCES

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| YMBOL | | | | | | | | |
| JRNAME | | | | | | | | |
| ATE | | | | | | | | |

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

34

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

March 8, 2006

Document Processing Desk
Antimicrobials Division (7510C)
US Environmental Protection Agency
Office of Pesticide Programs
Mr. Adam Heyward (PM34)
Room 266A, Crystal Mall #2
1801 S. Bell Street
Arlington, VA 22202-4501

**Subject: Virkon® S; EPA Registration No. 71654-6**
**Notification of Alternate Formulations PR Notice 98-10 (III.B.1.)**

Dear Mr. Heyward,

The purpose of this submission is to notify alternate Confidential Statements of Formula that have been previously submitted and accepted (Ref: Your letter of June 7, 2005).

We have added additional manufacturing cites to Block #6 of the CSFs. The secondary manufacturing cite will use substitute commodity chemicals from suppliers of the inerts as indicated on the appended, "Attachment to Confidential Statements of Formula; EPA Form Number 8570-4; EPA Registration No. 71654-6; Virkon® S and EPA Registration No. 71654-7; Virkon® (February 15, 2006)."

Therefore I respectively request that the following CSFs be substituted for the previously submitted and accepted corresponding CSF.

| March 8, 2006 Submission | Previous Submission Signed | Previously Accepted |
|---|---|---|
| Basic Formula | March 9, 2005 | June 7, 2005 |
| Alternate 25% dye | March 9, 2005 | June 7, 2005 |
| Alternate Fragrance & Dye Free | March 9, 2005 | June 7, 2005 |
| Alternate Fragrance Free | March 9, 2005 | June 7, 2005 |

This request is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

*Please read instructions on reverse before completing form.* Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

**EPA** United States Environmental Protection Agency Washington, DC 20460

☐ Registration ☐ Amendment X Other:

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number<br>71654-6 | 2. EPA Product Manager<br>Adam Heyward | 3. Proposed Classification<br>☐ None ☐ Restricted |
|---|---|---|
| 4. Company/Product (Name)<br>**Virkon® S** | PM#<br>34 | |
| 5. Name and Address of Applicant *(Include ZIP Code)*<br>**E.I. du Pont de Nemours and Company**<br>**Attn : Thomas C. McEntee**<br>**DuPont Chemical Solutions Enterprise, P.O. Box 80402**<br>**Wilmington DE 19880-0402**<br>***PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW***<br>☐ *Check if this is a new address* | 6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:<br>EPA Reg. No. _____<br>Product Name_____ | |

## Section - II

- ☐ Amendment – Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- X Notification - Explain below.
- ☐ Final printed labels in response to Agency letter dated _____
- ☐ "Me Too" Application
- ☐ Other - Explain below

**Explanation**: Use additional page(s) if necessary. (For Section I and Section II.)

Notification of Secondary Production in USA (8570-4; block #6) and locally sourced commodity inert ingredients

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject top enforcement action and penalties under sections 12 and 14 of FIFRA

## Section - III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes* ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) |
| ***Certification must be submitted*** | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt. / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☐ Label ☐ Container | | ☐ On Label ☐ On labeling accompanying product |

6. Manner In Which Label Is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

## Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| **Thomas C. McEntee** | **Product Registration Manager** | 302-695-6856 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| 2. Signature | 3. Title | 6. Date Application Received |
|---|---|---|
| Thomas C. McEntee | **Product Registration Manager** | **(Stamped)** |
| 4. Typed Name<br>Thomas C. McEntee | 5. Date<br>*March 8, 2006* | |

**EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete** **White- EPA File Copy (original) Yellow- Applicant Copy**

## RISK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | | |
|---|---|---|---|
| PRODUCT REVIEWER: P Whitaker | | | RMB II TEAM 34 |
| Description of Action: | | | EPA File Symbol/Reg No. 71654-6 |
| Decision No. 363289 | Submission No. 788260 | | Fee for Service Action Code: |
| FQPA Action Code: 332 | Non-FQPA Action Code: | | PRIA FEE AMOUNT: |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | 12 | 15 | 2005 |
| EPA PIN DATE | 12 | 19 | 2005 |
| REVIEWER ASSIGNED DATE | 12 | 20 | 2005 |
| DATE DUE FROM SCIENCE | | | |
| NEGOTIATED DUE DATE | | | 2006 |
| DATE DUE OUT OF AGENCY | | | |

| Type of Data: | PSB Product Chemistry | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure |
|---|---|---|---|---|---|---|---|

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM*

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only | |
|---|---|---|
| | Contract No.: 0411 | *ARCTIC SLOPE*/MANAGER |
| | Final Task: Signature _____ | _____ (Total hrs) |
| C | Reviewer's Comments: | |

DATE FEE PAID: | RESPONSE CODE: 18 RESPONSE DATE: 1/17/06

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 17, 2006

Thomas C. McEntee
Product Registration Manager
**Dupont Chemical Solutions Enterprise**
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: Notification in Accordance with PR Notice 98-10
**Virkon® S**
EPA Registration Number 71654-6
Application: December 15, 2005
Receipt Date: December 19, 2005

Dear Mr. McEntee:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

**Proposed Notification**:

- Deletion of pests that have not received acceptance in California.
- Narrowing of claims for use in presence of hardwater.

**General Comment**:

Based on a review of the material submitted, the following comment applies.

The notification application is acceptable. However, we have the following comments concerning the labeling submitted with this application.

1. The labeling which has not been reviewed per PR Notice 82-2 contains the claim for use by veterinary. The claim was rejected in EPA letter dated November 18, 2005 because it is associated with the organisms "*microsporus canis* and *trichophyton*" the causative agent for "ringworm".
2. The Agency considers these claims to be medical treatment and therefore is not acceptable on antimicrobial products.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

NOT REVIEWED
In accordance with PR Notice 93-2
Based on Draft Labeling Dated

Master Label
**Virkon® S**
**Virkon®** S Broad Spectrum Disinfectant [Alternate Brand Name]
**DuPont™ Virkon®** S Disinfectant and Virucide for Veterinary Applications[ABN]
**Virkon®** S Disinfectant and Virucide for Veterinary Applications [Alternate Brand Name]
**DuPont™ Virkon®** Aquatic Disinfectant and Virucide [Alternate Brand Name]

[Fragrance Free] [Reduced Dye] [Fragrance & Dye Free]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)

Effective against
•Viruses
(including CANINE PARVOVIRUS) [OPT]
•Bacteria
•Fungi

For Use in Emergency Disease Control (OPT.)

For use in Cleaning and Disinfecting Institutional and Service Facilities including stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters), e.g., cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment.(OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

| ACTIVE INGREDIENTS: | |
|---|---|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | 77.09% |
| TOTAL..... | 100.00% |

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO
See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

[For 1% solution, empty one 1.3 oz. sachet into 1 gal. water]

[TABLET FORM]

[POWDER FORM]

EPA Registration No. 71654-6

EPA Est. No. 62432-EN-001

Front Panel Continued

| FIRST AID | |
|---|---|
| **If in Eyes:** | $ Hold eye open and rinse slowly and gently with water for 15-20 minutes.<br>$ Remove contact lenses, if present after 5 minutes, then continue rinsing eye.<br>$ Call a Poison Control Center or doctor for further treatment advice. |
| **If on Skin or Clothing:** | $ Take off contaminated clothing.<br>$ Rinse skin immediately with plenty of water for 15-20 minutes.<br>$ Call a Poison Control Center or doctor for further treatment advice. |
| **If Swallowed:** | $ Call Poison Control Center or doctor immediately for treatment advice.<br>$ Have Person sip a glass of water if able to swallow.<br>$ Do not induce vomiting unless told to do so by the poison control center or doctor<br>$ Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| For 24-hour emergency information on this product, call 1-800-441-3637 (US & Canada) or 1-302-774-1139 (all other areas).<br>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| **Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage. | |

Net contents: _____ US Patent No. 4822512

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

**EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:**

**ANIMAL AND ZOONOTIC PATHOGENS**

**BACTERIA**

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

*Not approved in California for use against the following bacteria:*
Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycobacterium bovis
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

**VIRUSES**

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

*Not approved in California for use against the following viruses:*
Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

*Not approved in California cont.*
Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

**FUNGI**

*Not approved in California for use against the following fungi:*
Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

**PLANT PATHOGENS**

*Not approved in California for use against plant pathogens:*
Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

**HUMAN HEALTH PATHOGENS**

Escherichia coli
Klebsiella pneumoniae
Pseudomonas aeruginosa
Salmonella cholerasuis
Salmonella typhimurium
Staphylococcus aureus
Staphylococcus epidermidis
Trichophyton mentagrophytes (use 2% solution)

*Not approved in California for use against:*
Helicobacter pylori
Human Immunodeficiency Virus (HIV) Type 1 (on hard, non-porous surfaces)
Streptococcus pyogenes

**PRECAUTIONARY STATEMENTS**
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
**Corrosive statement refers to powder only not in use solution.**

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm AOAC hard water [200 ppm in California] and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution." Virkon® S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 400 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation. [OPT as the statement pertaining to the germicidal and detergent sanitizer test is not allowed in California].

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

## GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder or tablet formulation is easily diluted for use in manual or machine operations.

***Virkon® S DILUTION CHART***

***Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water.]***

***Powder***

| *Quantity of Water* | *0.5% Solution** | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Quart* | *0.15 ounces** | *0.3 ounces* | *0.7 ounces* |
| *1 Gallon* | *0.65 ounces** | *1.3 ounces* | *2.7 ounces* |
| *10 Gallons* | *6.7 ounces** | *13.4 ounces* | *26.7 ounces* |
| *50 Gallons* | *33.4 ounces** | *66.8 ounces* | *133.5 ounces* |

***Measuring cup provided.***

* The 0.5% solution currently is not approved for use in California.

***Tablet***

| *Quantity of Water* | *0.5% Solution** | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Pint* | | *1 tablet* | *2 tablets* |
| *1 Quart* | *1 tablet** | *2 tablets* | *4 tablets* |
| *1 Gallon* | *4 tablets** | *8 tablets* | *16 tablets* |

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

* The 0.5% solution currently is not approved for use in California.

POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI(molds and yeasts)Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori.] (OPT.)

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

## SWINE PRODUCTION

[CONTROLS: Bacteria of Actinobacillus Pleuropneumoniae and Clostridium perfringens;. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.] (OPT.)

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

## BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: *Not approved in California for use against the following organisms:* Fungi of Fusarium moniliforme.Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever)] (OPT.)

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

## BOVINE PRODUCTION

[CONTROLS: Bovine Adenovirus Type 4; Bacteria of Moraxella bovis and Mycobacterium bovis; Fungi of Fusarium moniliforme. *Not approved in California for use against the following organisms:* Bacteria of Moraxella bovis and Mycobacterium bovis; Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.] (OPT.)

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS

[CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.] (OPT.)

[APPLICATIONS] A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to remove organic deposits.*

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California:*: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

*Not approved for this use in California*

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

CONTROLS: *Not approved for this use in California* OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle

Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.
Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

*Not approved for this use in California*
The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon S may be used at the following dilution rates:

| Disease Organism | Dilution rate | Oz./Gal. |
|---|---|---|
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

## USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does <u>not</u> come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

INSTITUTIONAL AND SERVICE FACILITIES
(HUMAN HEALTH)

CONTROLS: Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces), Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Trichophyton mentagrophytes. (OPT.)

With Virkon® S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon® S solution on textiles or carpets. Virkon® S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

Cleaning and Disinfecting Non-Food Contact Surfaces: Remove gross dirt and use 1.0% Virkon® S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon® S solution.

Sanitizing Toilet Bowls: After flushing, sprinkle 1 oz. Virkon® S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

Cleaning and Disinfecting Manikins Used in CPR Training: Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon® S solution. Let stand for 10 minutes and rinse with potable water.

Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination: Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST *HIV-1 ON HARD NON-POROUS SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

*Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (Hospitals, Nursing Homes, etc.) or other settings in which there is an expected likelihood of soiling of hard non-porous surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable protective latex gloves, gowns, masks, and eye protection.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

## EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

## STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.
DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

DuPont Chemical Solutions Enterprise
P.O. Box 80705
Wilmington, DE 19880-0705

DuPont Chemical Solutions Enterprise

TRANSMITTAL LETTER

December 15, 2005

Document Processing Desk (NOTIF)
Antimicrobials Division (7510C)
US Environmental Protection Agency; OPP
Mr. Adam Heyward (PM34)
Room 266A, Crystal Mall #2
1801 S. Bell Street
Arlington, VA 22202-4501

Reference: Virkon ® S; EPA Registration No. 71654-6
Notification (PR 98-10 II.B Disclaim pests not approved by CDPR)

Dear Mr. Heyward,

Please find the attached application form 8570-1 for notification labeling disclaiming use against pests that have not received approval by the California Department of Pesticide Regulation (PR 98-10 B). The CDPR has also requested that EPA accept notification of disclaiming use in hard water that is >200 ppm and acceptance of instruction to "Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution" (PR 98-10 M.3).

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Accordingly, I have attached 5 copies of text format labeling. I have also attached a copy highlighting the changes from the most recently accepted, November 10, 2004 EPA stamped-accepted label.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 71654-6 | Adam Heyward | [X] None [ ] Restricted |
| **4. Company/Product (Name)** | **PM#** | |
| Virkon (R) S | 34 | |

**5. Name and Address of Applicant** *(Include ZIP Code)*

E.I. du Pont de Nemours and Company
Attn: Thomas C. McEntee
Dupont Chemical Solutions Enterprise, P. O. Box 80402
Wilmington, DE 19880-0402

[ ] *Check if this is a new address*

**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in repeonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of Deletion of pests that have not received acceptance in California. Narrowing of claims for use in presnce of hardwater.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| [ ] Yes | [ ] Yes | [ ] Yes | [ ] Metal |
| [X] No | [ ] No | [ ] No | [X] Plastic |
| *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | [ ] Glass<br>[ ] Paper<br>[ ] Other (Specify) _____ |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| [X] Label [ ] Container | 10 lb., 1lb., 9 oz. | [X] |

**6. Manner in Which Label is Affixed to Product** [X] Lithograph Paper glued Stenciled [ ] Other _____

## Section - IV

**1. Contact Point** *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Thomas C. McEntee | Product Registration Manager | 302 695 6856 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

**6. Date Application Received** (Stamped)

| 2. Signature | 3. Title |
|---|---|
| Thomas C. McEntee | Product Registration Manager |
| **4. Typed Name** | **5. Date** |
| Thomas C. McEntee | December 15, 2005 |

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Master Label
**Virkon® S**
**Virkon® S** Broad Spectrum Disinfectant [Alternate Brand Name]
**DuPont™ Virkon® S** Disinfectant and Virucide for Veterinary Applications[ABN]
**Virkon® S** Disinfectant and Virucide for Veterinary Applications [Alternate Brand Name]
**DuPont™ Virkon®** Aquatic Disinfectant and Virucide [Alternate Brand Name]

[Fragrance Free] [Reduced Dye] [Fragrance & Dye Free]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)

Effective against
•Viruses
(including CANINE PARVOVIRUS) [OPT]
•Bacteria
•Fungi

For Use in Emergency Disease Control (OPT.)

For use in Cleaning and Disinfecting Institutional and Service Facilities including stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters), e.g., cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment.(OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

| ACTIVE INGREDIENTS: | |
|---|---|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | 77.09% |
| TOTAL..... | 100.00% |

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO
See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

[For 1% solution, empty one 1.3 oz. sachet into 1 gal. water]

[TABLET FORM]

[POWDER FORM]

EPA Registration No. 71654-6 EPA Est. No. 62432-EN-001

Front Panel Continued

| FIRST AID | |
|---|---|
| **If in Eyes:** | $ Hold eye open and rinse slowly and gently with water for 15-20 minutes.<br>$ Remove contact lenses, if present after 5 minutes, then continue rinsing eye.<br>$ Call a Poison Control Center or doctor for further treatment advice. |
| **If on Skin or Clothing:** | $ Take off contaminated clothing.<br>$ Rinse skin immediately with plenty of water for 15-20 minutes.<br>$ Call a Poison Control Center or doctor for further treatment advice. |
| **If Swallowed:** | $ Call Poison Control Center or doctor immediately for treatment advice.<br>$ Have Person sip a glass of water if able to swallow.<br>$ Do not induce vomiting unless told to do so by the poison control center or doctor<br>$ Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| For 24-hour emergency information on this product, call 1-800-441-3637 (US & Canada) or 1-302-774-1139 (all other areas).<br>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| **Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage. | |

Net contents: _____ US Patent No. 4822512

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

**EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:**

**ANIMAL AND ZOONOTIC PATHOGENS**

**BACTERIA**

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

*Not approved in California for use against the following bacteria:*
Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycobacterium bovis
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

**VIRUSES**

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

*Not approved in California for use against the following viruses:*
Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

*Not approved in California cont.*
Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

**FUNGI**

*Not approved in California for use against the following fungi:*
Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

**PLANT PATHOGENS**

*Not approved in California for use against plant pathogens:*
Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

**HUMAN HEALTH PATHOGENS**

Escherichia coli
Klebsiella pneumoniae
Pseudomonas aeruginosa
Salmonella cholerasuis
Salmonella typhimurium
Staphylococcus aureus
Staphylococcus epidermidis
Trichophyton mentagrophytes (use 2% solution)

*Not approved in California for use against:*
Helicobacter pylori
Human Immunodeficiency Virus (HIV)
Type 1 (on hard, non-porous surfaces)
Streptococcus pyogenes

**PRECAUTIONARY STATEMENTS**
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
**Corrosive statement refers to powder only not in use solution.**

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm AOAC hard water [200 ppm in California] and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution." Virkon® S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 400 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation. [OPT as the statement pertaining to the germicidal and detergent sanitizer test is not allowed in California].

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

## GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder or tablet formulation is easily diluted for use in manual or machine operations.

***Virkon® S DILUTION CHART***

***Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water.]***

***Powder***

| *Quantity of Water* | *0.5% Solution** | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Quart* | *0.15 ounces** | *0.3 ounces* | *0.7 ounces* |
| *1 Gallon* | *0.65 ounces** | *1.3 ounces* | *2.7 ounces* |
| *10 Gallons* | *6.7 ounces** | *13.4 ounces* | *26.7 ounces* |
| *50 Gallons* | *33.4 ounces** | *66.8 ounces* | *133.5 ounces* |

***Measuring cup provided.***

* The 0.5% solution currently is not approved for use in California.

***Tablet***

| *Quantity of Water* | *0.5% Solution** | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Pint* | | *1 tablet* | *2 tablets* |
| *1 Quart* | *1 tablet** | *2 tablets* | *4 tablets* |
| *1 Gallon* | *4 tablets** | *8 tablets* | *16 tablets* |

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

* The 0.5% solution currently is not approved for use in California.

POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI(molds and yeasts)Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori.] (OPT.)

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

## SWINE PRODUCTION

[CONTROLS: Bacteria of Actinobacillus Pleuropneumoniae and Clostridium perfringens;. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.] (OPT.)

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

## BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: *Not approved in California for use against the following organisms:* Fungi of Fusarium moniliforme.Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever)] (OPT.)

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

## BOVINE PRODUCTION

[CONTROLS: Bovine Adenovirus Type 4; Bacteria of Moraxella bovis and Mycobacterium bovis; Fungi of Fusarium moniliforme. *Not approved in California for use against the following organisms:* Bacteria of Moraxella bovis and Mycobacterium bovis; Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.] (OPT.)

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS

[CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.] (OPT.)

[APPLICATIONS] A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to remove organic deposits.*

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California:*: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

*Not approved for this use in California*
Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

CONTROLS: *Not approved for this use in California* OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle

Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.
Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

*Not approved for this use in California*

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon S may be used at the following dilution rates:

| Disease Organism | Dilution rate | Oz./Gal. |
|---|---|---|
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does <u>not</u> come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

INSTITUTIONAL AND SERVICE FACILITIES
(HUMAN HEALTH)

CONTROLS: Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces), Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Trichophyton mentagrophytes. (OPT.)

With Virkon® S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon® S solution on textiles or carpets. Virkon® S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

Cleaning and Disinfecting Non-Food Contact Surfaces: Remove gross dirt and use 1.0% Virkon® S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon® S solution.

Sanitizing Toilet Bowls: After flushing, sprinkle 1 oz. Virkon® S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

Cleaning and Disinfecting Manikins Used in CPR Training: Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon® S solution. Let stand for 10 minutes and rinse with potable water.

Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination: Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST *HIV-1 ON HARD NON-POROUS SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

*Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (Hospitals, Nursing Homes, etc.) or other settings in which there is an expected likelihood of soiling of hard non-porous surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable protective latex gloves, gowns, masks, and eye protection.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

## EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

## STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

## RISK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | |
|---|---|---|
| PRODUCT REVIEWER: R Whitaker | | RMB II TEAM 34 |
| Description of Action: | | EPA File Symbol/Reg No. 71654-6 |
| Decision No. 363287 | Submission No. 788240 | Fee for Service Action Code: |
| FQPA Action Code: 372 | Non-FQPA Action Code: | PRIA FEE AMOUNT: |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | 12 | 15 | 2005 |
| EPA PIN DATE | 12 | 19 | 2005 |
| REVIEWER ASSIGNED DATE | 12 | 20 | 2005 |
| DATE DUE FROM SCIENCE | | | |
| NEGOTIATED DUE DATE | | | 2006 |
| DATE DUE OUT OF AGENCY | | | |

| Type of Data: | PSB Product Chemistry | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure |
|---|---|---|---|---|---|---|---|

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM*

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only | |
|---|---|---|
| | Contract No.: 0411 | *ARCTIC SLOPE*/MANAGER |
| | Final Task: Signature _____ | _____ (Total hrs) |
| C | Reviewer's Comments: | |

DATE FEE PAID: _____ RESPONSE CODE: 12 RESPONSE DATE: 1/17/06

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 17, 2006

Thomas C. McEntee
Product Registration Manager
**Dupont Chemical Solutions Enterprise**
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: Notification in Accordance with PR Notice 98-10
**Virkon® S**
EPA Registration Number 71654-6
Application: December 15, 2005
Receipt Date: December 19, 2005

Dear Mr. McEntee:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

**Proposed Notification**:

- Additional Brand Name: **DuPont™ Virkon® S Disinfectant and Virucide for Veterinary Use**

**General Comment**:

Based on a review of the material submitted, the following comment applies.

The notification application is not acceptable for the following reasons:

- The basic product labeling [MASTER LABELING] do not list "Veterinary" as an approved claim. Although it lists Agricultural Facilities as a use cite, the MASTER labeling must be amended to include "Veterinary cite" before it can be accepted as an additional brand name. Refer to EPA letter dated November 18, 2005.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Renae A. Whitaker

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

39

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

TRANSMITTAL LETTER

December 15, 2005

Document Processing Desk (NOTIF)
Antimicrobials Division (7510C)
US Environmental Protection Agency
Office of Pesticide Programs
Mr. Adam Heyward (PM34)
Room 266A, Crystal Mall #2
1801 S. Bell Street
Arlington, VA 22202-4501

Reference: Virkon ® S
EPA Registration No. 71654-6
Alternate Brand Name (PR 98-10 II.A)

Dear Mr. Heyward,

Please find the attached application form 8570-1 for notification of an additional brand name:

DuPont ™ Virkon ® S Disinfectant and Virucide for Veterinary Use

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

*Please read instructions on reverse before completing form.*

Form Approved. OMB No. 2070-0060

| EPA | United States Environmental Protection Agency Washington, DC 20460 | [ ] Registration [ ] Amendment [X] Other | OPP Identifier Number |
|---|---|---|---|

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 71654-6 | Adam Heyward | [X] None [ ] Restricted |
| **4. Company/Product (Name)** | **PM#** | |
| Virkon (R) S | 34 | |

**5. Name and Address of Applicant** *(Include ZIP Code)*

E.I. du Pont de Nemours and Company
Attn: Thomas C. McEntee
Dupont Chemical Solutions Enterprise, P. O. Box 80402
Wilmington, DE 19880-0402

[ ] *Check if this is a new address*

**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand Name per PR Notice 98-10 DuPont (TM) Virkon (R) S Disinfectant and Virucide for Veterinary Use

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| [ ] Yes [X] No | [ ] Yes [ ] No | [ ] Yes [ ] No | [ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____ |
| *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| [X] Label [ ] Container | 10 lb., 1lb., 9 oz. | X |

**6. Manner in Which Label is Affixed to Product** [x] Lithograph Paper glued Stenciled [ ] Other _____

## Section - IV

**1. Contact Point** *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Thomas C. McEntee | Product Registration Manager | 302 695 6856 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| 2. Signature | 3. Title | 6. Date Application Received |
|---|---|---|
| Thomas C. McEntee | Product Registration Manager | (Stamped) |
| **4. Typed Name** | **5. Date** | |
| Thomas C. McEntee | December 15, 2005 | |

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

# TASK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | | |
|---|---|---|---|
| PRODUCT REVIEWER: Sarey | | RMB II | TEAM 34 |
| Description of Action: | | EPA File Symbol/Reg No. 7164-4 | |
| Decision No. 362347 | Submission No. S- 766679 | Fee for Service Action Code: | |
| FQPA Action Code: 332 | Non-FQPA Action Code: | PRIA FEE AMOUNT: | |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | ~~September~~ 11 | 02 | 2005 |
| ~~EF~~ IN DATE | ~~September~~ 11 | 07 | 2005 |
| REVIEWER ASSIGNED DATE | ~~October~~ 11 | 17 | 2005 |
| DATE EXTENDED | | | |
| DATE DUE TO PM | | | |
| DATE DUE OUT OF AGENCY | | | 2005 |

| Type of Data: | PSB Product Chemistry | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure |
|---|---|---|---|---|---|---|---|

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM*

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only | | |
|---|---|---|---|
| Contractor: Arctic Slope | | Contract No.: 0411 | *ARCTIC SLOPE/MANAGER* |
| Draft Task: Signature _____ | _____ (Est. hrs) | Final Task: Signature [signature] 15 (Total hrs) | |

| C | Reviewer's Comments: |
|---|---|

| DATE FEE PAID: | RESPONSE CODE 19 RESPONSE DATE: 11/29/05 |
|---|---|
| | |

DuPont Chemical Solutions Enterprise
P.O. Box 80840
Wilmington, DE 19880-0840

DuPont Chemical Solutions Enterprise

TRANSMITTAL LETTER

November 2, 2005

Document Processing Desk (NOTIF)
Antimicrobials Division (7510C)
US Environmental Protection Agency
Office of Pesticide Programs
Mr. Adam Heyward (PM34)
Room 266A, Crystal Mall #2
1801 S. Bell Street
Arlington, VA 22202-4501

Reference: Virkon ® S
EPA Registration No. 71654-6
Alternate Brand Name (PR 98-10 II.A)

Dear Mr. Heyward,

Please find the attached application form 8570-1 for notification of an additional brand name:
DuPont ™ Virkon ® S Disinfectant and Virucide

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

copy to M. Sherrill 11-7-05

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number: 71654-6

2. EPA Product Manager: Adam Heyward

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): Virkon (R) S

PM#: 34

5. Name and Address of Applicant *(Include ZIP Code)*

E.I. du Pont de Nemours and Company
Attn: Thomas C. McEntee
Dupont Chemical Solutions Enterprise, P. O. Box 80402
Wilmington, DE 19880-0402

[X] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in reponse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand Name per PR Notice 98-10 DuPont (TM) Virkon (R) S Disinfectant and Virucide

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I furhter understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: [ ] Yes [X] No
*Certification must be submitted*

Unit Packaging: [ ] Yes [ ] No
If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging: [ ] Yes [ ] No
If "Yes" Package wgt / No. per container

2. Type of Container: [ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container: 10 lb., 1lb., 9 oz.

5. Location of Label Directions: [X]

6. Manner in Which Label is Affixed to Product: [x] Lithograph / Paper glued / Stenciled [ ] Other _____

## Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Thomas C. McEntee | Product Registration Manager | 302 695 6856 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

8. Date Application Received (Stamped)

2. Signature: Thomas C. McEntee

3. Title: Product Registration Manager

4. Typed Name: Thomas C. McEntee

5. Date: November 1, 2005

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 29, 2005

Thomas C. McEntee
Product Registration Manager
Dupont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: Virkon® S
EPA Registration No. 71654-6
Application Date: November 2, 2005
EPA Received Date: November 7, 2005

Dear Mr. McEntee:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification**

- Alternate Brand Name "DuPont™ Virkon® S Disinfectant and Virucide"

**General Comments**

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

| CONCURRENCES | | | | | | | |
|---|---|---|---|---|---|---|---|
| SYMBOL | 7510C | | | | | | |
| SURNAME | LBarr | | | | | | |
| DATE | 11-29-05 | | | | | | |

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

## TASK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | | |
|---|---|---|---|
| PRODUCT REVIEWER: Lisa McKelvin | | RMB II | TEAM 34 |
| Description of Action: | | EPA File Symbol/Reg No. 71654-6 | |
| Decision No. 362258 | Submission No. S-~~706189~~ | Fee for Service Action Code: | |
| FQPA Action Code: 309 | Non-FQPA Action Code: | PRIA FEE AMOUNT: | |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | ~~September~~ 11 | 01 | 2005 |
| PIN DATE | ~~September~~ 11 | 02 | 2005 |
| REVIEWER ASSIGNED DATE | ~~October~~ 11 | 15 | 2005 |
| DATE EXTENDED | | | |
| DATE DUE TO PM | | | |
| DATE DUE OUT OF AGENCY | | | 2005 |

| Type of Data: | PSB Product Chemistry | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure |
|---|---|---|---|---|---|---|---|

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM*

Lisa: See me on this

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only | |
|---|---|---|
| Contractor: Arctic Slope | Contract No.: 0411 | *ARCTIC SLOPE*/MANAGER |
| Draft Task: Signature _____ _____ (Est. hrs) | Final Task: Signature _____ _____ (Total hrs) | |

| C | Reviewer's Comments: |
|---|---|

| DATE FEE PAID: | RESPONSE CODE: 11 RESPONSE DATE: 11/18/05 |
|---|---|
| | |

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**Washington, D.C. 20460**

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

**November 18, 2005**

Thomas C. McEntee
Product Registration Manager
**E. I. DUPONT De Nemours and Company**
Post Office Box 80023
Wilmington, Delaware 19880-0023

Subject: **VIRKON**
EPA Registration No. 71654-7
Letter Date: November 1, 2005
Receipt Date: November 2, 2005

Dear Mr. McEntee:

The following amendment, submitted in connection with registration under section the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable for the reasons listed below:

**Proposed Amendment:**

- Revised labeling [add directions for use by veterinarians for microsporus canis and trchophyton on dogs, cats, and horses]

**General Comments:**

Although the above microorganisms are not public health microorganisms, the animals [dogs, cats and horses] being treated are considered to be domestic animals, which will come in contact with humans. Therefore, efficacy data must be submitted to support the proposed claims.

Should you have any questions or comments concerning this letter, please contact Lisa Mckelvin at (703) 308-7496 or me at (703) 308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

TRANSMITTAL LETTER

November 1, 2005

Document Processing Desk
Antimicrobials Division (7510C)
US Environmental Protection Agency
Office of Pesticide Programs
Mr. Adam Heyward (PM34)
Room 266A, Crystal Mall #2
1801 S. Bell Street
Arlington, VA 22202-4501

Reference: Virkon ® S
EPA Registration No. 71654-6
Application to Amend labeling – Trichophyton and Microsporum

Dear Mr. Heyward,

This letter and its attachments are to amend the subject registration to include the use of the product in the management of Trichophyton and Microsporum organisms, the causative agents of "ringworm" in non-food producing animals, including dogs, cats and horses.

Please refer to the attached:

1. Application for Amended Registration (8570-1)
2. FRA-EPA Memo of Understanding "Mutual Responsibilities under FFDCA and FIFRA" 10/01/80
3. Letter from Veterinary Medicines Directorate (UK) June 11, 2003 "TOPICAL USE"
4. Virkon ® S Amended labeling in WORD (15 pages)
5. EPA Data Matrix (8570-35)
6. EPA Certification with Respect to Citation of Data (8570-34)

Further to this subject:

The claim is limited to disinfection of the coat and hair of the animals.
There is no suggestion that the product is used as the treatment of the disease "ringworm".
The use site is limited to non-food producing animals.
In accordance with PR Notice 96-6, the product is not for use on animals under 12 weeks of age and reapplication is once per week.

**USE BY VETERINARIANS IN THE MANAGEMENT OF TRICHOPHYTON AND MICROSPORUM**

**Virkon ® S is a broad spectrum antifungal disinfectant against Microsporum canis and trichophyton spp. [Washing/rinsing the animals hair/coat/fur with a 1:100 dilution of Virkon ® S *can reduce the skin challenge due to pathogenic fungal organisms.*](OPT.)**

**Only for application to the hair/coat/fur of dogs, cats and horses. (not for use on food producing animals). Do not apply to animals less than 12 weeks of age. Do not re-apply more than once per week.**

**Prepare a 1% solution of Dupont (TM) Virkon (R) S in clean water. Using a clean sponge or cloth, apply Virkon S solution to saturate the coat of the animal, ensure that the disinfectant solution is kept out of the animals eyes, ears and respiratory tracts. Leave for ten minutes and then rinse the animals coat thoroughly with clean water. If re-treatment is necessary, wait at least 7 days.**

Virkon ® S has a LD50 of 4123 mg/kg body weight and is considered slightly toxic to animals. The product is corrosive to animals, however the use diluted product is not significantly irritating to animal skin or eyes. (Nevertheless, use of protective glovewear and eyewear is recommended).

Potassium peroxymonosulfate, the active ingredient in Virkon ® S, has been tested for subchronic oral toxicity in rats. The No Observable Adverse Effects level was 200 mg/kg body weight. The Lowest Observable Adverse Effects Level is 600 mg/kg body weight.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntec
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 4, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THOMAS C. MCENTEE
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE DIVISION
BMP 23/2161, PO Box 80023
WILMINGTON, DE 19880-

PRODUCT NAME: VIRKON S
COMPANY NAME: E.I. DUPONT DE NEMOURS AND COMPANY
EPA FILE SYMBOL: 71654-6
EPA RECEIPT DATE: 11/02/05

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at (703) 308-6422.

Sincerely,

J. Price

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 71654-6 | Adam Heyward | [X] None [ ] Restricted |
| **4. Company/Product (Name)** | **PM#** | |
| Virkon (R) S | 34 | |

**5. Name and Address of Applicant** *(Include ZIP Code)*

E.I.du pont de Nemours & Company
Dupont Chemical Solutions Enterprise, P. O. Box 80403
Wilmington, DE 19880-0403

[ ] *Check if this is a new address*

**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in reponse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Add directions for use by Veterinarians in the management of Microsporus canis and trichophyton on Dogs, cats and horses

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| [ ] Yes [X] No | [ ] Yes [ ] No | [ ] Yes [ ] No | [ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____ |
| *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| [X] Label [ ] Container | 10 lb., 1lb., 9 oz. | [X] |

**6. Manner in Which Label is Affixed to Product** [x] Lithograph Paper glued Stenciled [ ] Other _____

## Section - IV

**1. Contact Point** *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Thomas C. McEntee | Product Registration Manager | 302 695 6856 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

**6. Date Application Received** (Stamped)

| 2. Signature | 3. Title | 4. Typed Name | 5. Date |
|---|---|---|---|
| Thomas C. McEntee | Product Registration Manager | Thomas C. McEntee | November 1, 2005 |

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460



## Certification with Respect to Citation of Data

| Applicant's/Registrant's Name, Address, and Telephone Number | EPA Registration Number/File Symbol |
|---|---|
| E.I. duPont de Nemours and Company, P. O. Box 80403 Wilmington, DE 19880-0403 | 71654-6 |
| Active Ingredient(s) and/or representative test compound(s) | Date |
| potassium peroxymonosulfate, sodium chloride | November 1, 2005 |
| General Use Pattern(s) (List all those claimed for this product using 40 CFR Part 158) | Product Name |
| Indoor | Virkon (R) S |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

### SECTION I. METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

### SECTION II. GENERAL OFFER TO PAY

Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

### SECTION III. CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that: (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered: (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product for noncompliance with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| Signature | Date | Typed or Printed Name and Title |
|---|---|---|
| Thomas C. McEntee | November 1, 2005 | Thomas C. McEntee/Product Registration Manager |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

| Date | | | EPA Reg No./File Symbol 71654-6 | | Page 1 of 1 |
|---|---|---|---|---|---|
| Applicant's/Registrant's Name & Address<br>E.I. duPont de Nemours and Company P. O. box 80402<br>Wilmington. DE 19880-0403 | | | Product<br>Virkon (R) S | | |
| Ingredient Chlorine Dioxide | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 82-1 (870.3100) | subchronic oral toxicity in rats (K peroxymonosulfate) | 46119007 | Antec Internation Inc | own | |
| 81-3 (870.1300) | Acute Inhalation Toxicidty (k peroxymonosulfate) | 46119006 | " | own | |
| 81-1 (870.1100) | Acute Oral Toxicidty | 46119004 | Antec | own | |
| 81-1 (870.1100) | Acute Oral Toxicity (k peroxymonosulfate) | 46119012 | Antec | | |
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| Signature | | | Name and Title<br>Thomas C. McEntee, Product Registration Manager | | Date<br>Nov. 1, 2005 |

*EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.*

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

| Date | EPA Reg No./File Symbol 71654-6 | Page 1 of 1 |
|---|---|---|
| Applicant's/Registrant's Name & Address<br>E.I. duPont de Nemours and Company P. O. box 80402 | Product<br>Virkon (R) S | |

Ingredient Chlorine Dioxide

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| [redacted] | | | Antec Internation Inc | own | |
| | | | " | own | |
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| Signature | Name and Title | Date |
|---|---|---|
| Thomas C. McEntee | Thomas C. McEntee, Product Registration Manager | Nov. 1, 2005 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

**Public File Copy**

11 JUN 2003

ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

Mr A Deeks
Antec International Ltd
Windham Road
Sudbury
Suffolk
CO10 2XD

Our ref: ULM04619

9 June 2003

Dear Mr Deeks

Please accept this letter as confirmation that the following text is acceptable for use in connection with the marketing of the product Virkon S solution.

Topical Use

Virkon® S can be used as a skin disinfectant.

Washing your horse with Virkon® S at a dilution rate of 1:100 can reduce the skin challenge of the organisms that are responsible for Ringworm, Mud Fever and Strangles.

Use a clean sponge or cloth to apply the Virkon® S solution to the coat of the horse, ensure that solution is kept out of the animal's eyes, ears and respiratory tracts. Leave for ten minutes and then rinse thoroughly with clean water.

Yours sincerely

Barry Haycraft
Enforcement and Feed Additives Team

**Veterinary Medicines Directorate**
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone (01932) 336911 Fax (01932) 336618 Website: www.vmd.gov.uk
Director and Chief Executive **Steve Dean** BVet Med DVR MRCVS

Master Label

# Virkon® S

DuPont™Virkon® S (OPT)

DISINFECTANT AND VIRUCIDE FOR VETERINARY APPLICATIONS [OPT.]

[OPT.] BROAD SPECTRUM DISINFECTANT[, FUNGICIDE & ALGAECIDE]

[Fragrance Free] [Reduced Dye] [Fragrance & Dye Free]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)

Effective against Viruses
(including CANINE PARVOVIRUS) ! Bacteria ! Fungi

For Use in Emergency Disease Control (OPT.)

For use in Cleaning and Disinfecting Institutional and Service Facilities including stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters), e.g., cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment.(OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

| ACTIVE INGREDIENTS: | |
|---|---|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | 77.09% |
| TOTAL..... | 100.00% |

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO
See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

[For 1% solution, empty one 1.3 oz. sachet into 1 gal. water]

[TABLET FORM]

[POWDER FORM]

Front Panel Continued

| FIRST AID | |
|---|---|
| **If in Eyes:** | $ Hold eye open and rinse slowly and gently with water for 15-20 minutes.<br>$ Remove contact lenses, if present after 5 minutes, then continue rinsing eye.<br>$ Call a Poison Control Center or doctor for further treatment advice. |
| **If on Skin or Clothing:** | $ Take off contaminated clothing.<br>$ Rinse skin immediately with plenty of water for 15-20 minutes.<br>$ Call a Poison Control Center or doctor for further treatment advice. |
| **If Swallowed:** | $ Call Poison Control Center or doctor immediately for treatment advice.<br>$ Have Person sip a glass of water if able to swallow.<br>$ Do not induce vomiting unless told to do so by the poison control center or doctor<br>$ Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| In case of emergency call 1 800 441 7515. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| **Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage. | |

Net contents:

EPA Reg. No. 71654-6 EPA Est. No. 62432-EN-001

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

Virkon® S is a registered trademark of and manufactured by Antec International Ltd.
a DuPont Company

US Patent No. 4822512

[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

**EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:**

**ANIMAL AND ZOONOTIC PATHOGENS**

**BACTERIA**

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

*Not approved in California for use against the following bacteria:*
Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycobacterium bovis
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

**VIRUSES**

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Infectious Bronchitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

*Not approved in California for use against the following viruses:*
Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

*Not approved in California cont.*
Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

**FUNGI**
Fusarium moniliforme
Trichophyton mentagrophytes (use 2% solution)

*Not approved in California for use against the following fungi:*
Aspergillus fumigatus
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

**PLANT PATHOGENS**
*Not approved in California for use against plant pathogens:*
Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

**HUMAN HEALTH PATHOGENS**

Escherichia coli
Klebsiella pneumoniae
Pseudomonas aeruginosa
Salmonella cholerasuis
Salmonella typhimurium
Staphylococcus aureus
Staphylococcus epidermidis
Trichophyton mentagrophytes (use 2% solution)

*Not approved in California for use against*:
Helicobacter pylori
Human Immunodeficiency Virus (HIV) Type 1 (on hard, non-porous surfaces)
Streptococcus pyogenes

**PRECAUTIONARY STATEMENTS**
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
**Corrosive statement refers to powder only not in use solution.**

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution." Virkon (R)® S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 400 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

## GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder or tablet formulation is easily diluted for use in manual or machine operations.

***Virkon® S DILUTION CHART***

***Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water.]***

***Powder***

| *Quantity of Water* | *0.5% Solution** | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Quart* | *0.15 ounces** | *0.3 ounces* | *0.7 ounces* |
| *1 Gallon* | *0.65 ounces** | *1.3 ounces* | *2.7 ounces* |
| *10 Gallons* | *6.7 ounces** | *13.4 ounces* | *26.7 ounces* |
| *50 Gallons* | *33.4 ounces** | *66.8 ounces* | *133.5 ounces* |

***Measuring cup provided.***

* The 0.5% solution currently is not approved for use in California.

*Tablet*

| *Quantity of Water* | *0.5% Solution** | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Pint* | | *1 tablet* | *2 tablets* |
| *1 Quart* | *1 tablet** | *2 tablets* | *4 tablets* |
| *1 Gallon* | *4 tablets** | *8 tablets* | *16 tablets* |

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

* The 0.5% solution currently is not approved for use in California.

POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Avian Laryngotracheitis and Avian Influenza; FUNGI(molds and yeasts)Aspergillus flavus Bacteria of Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium.] (OPT.)

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved use in California:* Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

## SWINE PRODUCTION

[CONTROLS: Bacteria of Actinobacillus Pleuropneumoniae and Clostridium perfringens;. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.] (OPT.)

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

## BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: *Not approved in California for use against the following organisms:* Fungi of Fusarium moniliforme.Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever)] (OPT.)

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

[CONTROLS: Bovine Adenovirus Type 4; Bacteria of Moraxella bovis and Mycobacterium bovis; Fungi of Fusarium moniliforme. *Not approved in California for use against the following organisms:* Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.] (OPT.)

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

[CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.] (OPT.)

[APPLICATIONS] A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

**[USE BY VETERINARIANS IN THE MANAGEMENT OF TRICHOPHYTON AND MICROSPORUM**

**Virkon ® S is a broad spectrum antifungal disinfectant against Microsporum canis and trichophyton spp. [Washing/rinsing the animals hair/coat/fur with a 1:100 dilution of Virkon ® S can reduce the skin challenge due to pathogenic fungal organisms.](OPT.)**

**Only for application to the hair/coat/fur of dogs, cats and horses. (not for use on food producing animals). Do not apply to animals less than 12 weeks of age. Do not re-apply more than once per week.**

**Prepare a 1% solution of Dupont (TM) Virkon (R) S in clean water. Using a clean sponge or cloth, apply Virkon S solution to saturate the coat of the animal, ensure that the disinfectant solution is kept out of the animals eyes, ears and respiratory tracts. Leave for ten minutes and then rinse the animals coat thoroughly with clean water. If re-treatment is necessary, wait at least 7 days.] (OPT).**

## GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California:*: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## AQUACULTURE

*Not approved use in California*

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

*Not approved use in California*

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

*Not approved use in California*

The instructions above call for use of a 1% solution for general disinfection, however, Virkon S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon S may be used at the following dilution rates:

| Disease Organism | Dilution rate | Oz./Gal. |
|---|---|---|
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

## USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon S to pool on surfaces that may be within reach of animals. Do not allow Virkon S to come into direct contact with people. Allow Virkon S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

## INSTITUTIONAL AND SERVICE FACILITIES (HUMAN HEALTH)

CONTROLS: Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces), Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Trichophyton mentagrophytes. (OPT.)

With Virkon® S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon® S solution on textiles or carpets. Virkon® S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

Cleaning and Disinfecting Non-Food Contact Surfaces: Remove gross dirt and use 1.0% Virkon® S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of

fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon® S solution.

Sanitizing Toilet Bowls: After flushing, sprinkle 1 oz. Virkon® S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

Cleaning and Disinfecting Manikins Used in CPR Training: Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon® S solution. Let stand for 10 minutes and rinse with potable water.

Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination: Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST *HIV-1 ON HARD NON-POROUS SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

*Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (Hospitals, Nursing Homes, etc.) or other settings in which there is an expected likelihood of soiling of hard non-porous surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable protective latex gloves, gowns, masks, and eye protection.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

## EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

## STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

SUBJECT: MOU with EPA regarding mutual responsibilities under FFDCA and FIFRA (FDA-225-73-8010).

MEMORANDUM OF UNDERSTANDING

Between The

ENVIRONMENTAL PROTECTION AGENCY

And The

U. S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
FOOD AND DRUG ADMINISTRATION

Reorganization Plan No. 3 of 1970 published in the Federal Register of October 6, 1970, stated in section 2, paragraph (4) that the functions vested in the Secretary of Health, Education and Welfare of establishing tolerances for pesticide chemicals under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 346, 346a, and 348, were transferred to the Administrator of the Environmental Protection Agency effective December 2, 1970. After considering all of the various pesticide uses which have been subject to petition procedures under these three sections, and certain other pesticide uses subject both to the Federal Insecticide, Fungicide, and Rodenticide Act, 731 U.S.C. 35, and to the Federal Food, Drug, and Cosmetic Act, the Administrator of the Environmental Protection Agency and the Secretary of Health, Education and Welfare have concluded that this agreement is needed to provide for the coordination of activities pertaining to pesticides and to inform all concerned as to which agency will process the pesticide petitions for each type of use.

Reorganization Plan No. 3 also transferred to the Administrator of the Environmental Protection Agency the functions of the Secretary of Agriculture under the Federal Insecticide, Fungicide, and Rodenticide Act. There are certain products which are subject to the requirements of both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In the past, confusion, misunderstanding and inconvenience have resulted from procedures followed in connection with the proposed marketing of such products. The Administrator of the Environmental Protection Agency (EPA) and the Secretary of Health,

Education, and Welfare are agreed that a new procedure should be followed whereby the manufacturer would be informed:

(1) of the agency exercising primary jurisdiction regarding his product,

(2) that the matter will be referred to the other agency for decision under the law of that agency, and

(3) that approval for marketing the product will not be granted unless or until each agency has approved the marketing under its respective authority.

This matter was the subject of a proposed statement of general policy and interpretation published in the Federal Register on August 5, 1970.

There are other procedures which should be established in order to facilitate the handling of matters which are of direct concern to both Agencies. These matters involve issuance of regulations under section 406 of the FFDCA, establishment of reference standards, exchange of information on certain programs, agreements with States and foreign countries on surveillance and enforcement activities on pesticide residues in food and publication of the Pesticide Analytical Manual.

The term "pesticide chemical" is defined in section 201(q) of the Federal Food, Drug, and Cosmetic Act as a substance which is a "pesticide" *** under the Federal Insecticide, Fungicide, and Rodenticide Act and which is used in the production, storage, or transportation of raw agricultural commodities. Pesticides used on food crops before or after harvest and on food animls are included in this category. Pesticides used on or concentrating in processed foods are treated in the Federal Food, Drug, and Cosmetic Act as food additives rather than pesticide chemicals.

Both agencies agree that:

1. The following petitions will be processed by the Environmental Protection Agency:

   a. Petitions requesting tolerances or exemption from tolerances for residues of pesticide chemicals on raw agricultural commodities.

   b. Petitions for food additive regulations required for residues of pesticide chemicals carrying over and concentrating in processed foods manufactured from treated raw agricultural commodities.

c. Petitions for regulations for residues of pesticides from direct treatment of processed foods with funigamts or insecticides.

d. Petitions for food additive regulations to permit the safe use of pesticides to impregnate food-packaging materials such as wrappers or bags to protect raw agricultural commodities from any pest or to protect processed foods from insects.

2. The following petitions will be processed by FDA:

a. Petitions for food additive regulations to permit use of sanitizers on food-contact surfaces.

b. Petitions for food additive regulations to permit the safe use of pesticides as preservatives in processed food.

c. Petitions for food additive regulations to permit the safe use of pesticides in food packaging material when such use is not covered by 1.d.

3. Applications for approval of drugs under FFDCA and for registration of pesticides under FIFRA will be processed as follows:

a. Whenever a product is submitted to either FDA or EPA for approval and it is believed by either agency that the product is subject to the requirements of both the FFDCA and the FIFRA, an interagency determination will be made and an agreement reached with respect to (1) whether the product is subject to the requirements of the FFDCA and FIFRA, (2) whether particular claims are "pesticide" or "drug" claims and (3) whether the representations made for the product, including the implications to be drawn therefrom, are primarily "pesticide" or "drug" representations.

b. Whenever application is made to EPA for registration of a product that is both a drug and a pesticide and determination has been made that the principal claims or representations relate to a pesticide, EPA will withhold registration of the product under FIFRA until it has been informed by FDA that the product complies with the provisions of the laws administered by FDA.

c. Whenever application is made to FDA for approval of a product that is both a drug and a pesticide and determination has been made that the principal claims or representations relate to a drug, FDA will not approve a new drug application, a new animal drug application or an antibiotic application without first being advised by EPA that the claims or representations subject to the provisions of the FIFRA are warranted and that the product is eligible for registration under that act.

d. Whenever application is made to EPA for the registration of a product that is both a drug and a pesticide and determination has been made that the principal claims or representations relate to a drug, the matter will be referred by EPA to FDA and the matter will thereafter be handled as if the application had been originally made to FDA.

e. Whenever application is made to FDA for approval of a product that is both a pesticide and a drug and determination has been made that the principal claims or representations relate to a pesticide, the matter will be referred by FDA to EPA and the matter will thereafter be handled as if the application had been originally made to EPA.

f. Neither agency will approve the marketing of a product under the law administered by it if the product would not be in full compliance with the requirements of a law administered by the other.

NOTE: The following paragraphs (g thru n) were added by amendment effective August 28, 1973.

g. Submissions for approval will be to the agency having primary jurisdiction in the format required by that agency which will be considered acceptable by the other agency in lieu of that normally required. Where specific requirements of the two agencies conflict in matters such as manufacturing, formulation, and labeling, the requirements of the agency of primary jurisdiction will apply.

h. The application of a product for any of, but not necessarily limited to, the uses listed below is considered to be both a human drug and a pesticide. The agency for primary jurisdiction regarding such products will be FDA and secondarily EPA.

i) Pediculicides and scabicides intended to control parasites on humans.

ii) Products intended to relieve the effect of insect bites on humans which also claim to repel the insects causing such bites.

iii) Products intended to prevent diaper rash by treatment of diapers.

iv) Fungicides for human use, i.e., athlete's foot which also claim to destroy such fungus on inanimate objects.

i. The application of a product for any of, but not necessarily limited to, the uses listed below is considered to be both a pesticide and human drug. The agency for primary jurisdiction regarding such products will be EPA and secondarily FDA.

Disinfectants and sanitizers intended for use on inanimate objects but including claims for use on humans.

j. Certain pesticides subject to the laws administered by EPA are also deemed to be animal drugs and subject to the laws administered by FDA under, but not necessarily limited to, the following conditions:

i) Products for oral administration such as tablets, boluses, drinking water preparations, medicated blocks, and medicated feeds, including liquid feeds and supplements (these do not apply to articles solely for the control of fecal breeding flies, nor solely for sanitizing the drinking water of animals).

ii) Products administered parenterally.

iii) Products which are absorbed through the skin surface as in demodectic mange conditions.

iv) Products introduced into wound or body openings, except for screwworms control, including application to the ear canal, for the control of ear mites; such conditions often require supportive treatment.

v) Products applied topically for their systemic action in an animal.

k. The application of a pesticide for any of the uses listed below is considered to be both an animal drug and a pesticide. The agency for primary jurisdiction regarding such articles will be FDA, except in those cases where the drug use is regarded as not a new animal drug. In this event, since FDA has no preclearance requirements for products so considered, the submission for registration will be to EPA. However, the product will not be registered until EPA has been notified by FDA that the product is in compliance with the requirements of the FFDCA.

i) Treatments for control of horse bots.

ii) Treatments that are administered orally or parenterally for control of cattle grubs.

iii) Treatments for control of demodectic mange mites.

iv) Treatments that are administered orally or parenterally for control of fleas (or other external parasites).

v) Treatments for control of ear mites.

vi) Treatments for control of ticks if the product labeling includes claims for control of ear mites.

vii) Aquatic treatments intended to control parasites and/or disease of fish in ponds or aquariums.

viii) Animal drinking water treatments with direct or implied claims for control of animal parasites or diseases.

ix) Any other product with a mode of action similar to that under j.

1. The application of a pesticide for any of the uses listed below will be regarded solely as a pesticide usage except where it has an action described in j, in which case it is considered to be both an animal drug and a pesticide. In these cases, the agency for primary jurisdiction will be EPA.

i) Treatments that are administered topically for control of cattle grubs which include application by spray, dip, pour-on, spot-on, back rubber or dust.

ii) Treatments for control of screwworms that are administered topically.

iii) Treatments for control of wool maggots that are administered topically.

iv) Treatments for control of horn fly or face fly that are administered topically.

v) Treatments for control of sarcoptic, psoroptic, and chorioptic mange mites that are administered topically.

vi) Treatments that are administered topically, for control of ticks except as listed in item k. (vi).

vii) Treatments for control of sheep keds that are administered topically.

viii) Treatments for control of fleas that are administered topically.

ix) Treatments that are administered orally solely for control of horn fly and/or face fly in cattle manure.

x) Aquatic treatments of ponds or aquariums solely for control of algae or bacterial slime and any other aquatic treatments solely for pest control which do not include claims for control of parasites or diseases of fish.

xi) Sanitizers intended to sanitize aquarium equipment.

xii) Sanitizers applied to inanimate surfaces and/or in drinking water of animals that do not include any direct or implied claims to control disease.

m. If a product that is subject to joint jurisdiction is deemed to be either a new human or animal drug, prior to registration by EPA, it must be in full compliance with the requirements for FDA approval of a new drug application, to include publication of its approval where required by the FFDCA (i.e., new animal drug), regardless of the agency of primary jurisdiction.

n. If a manufacturer proposing a new product is unable to determine the agency of primary jurisdiction, a presubmission inquiry may be submitted to either agency. FDA and EPA will jointly consider the inquiry and advise the manufacturer of their conclusions in this matter.

4. If the poisonous or deleterious substance referred to in section 406 of the Federal Food, Drug, and Cosmetic Act is present in food primarily as a result of its use as a pesticide chemical, or a pesticide, any regulation establishing a tolerance for such substance in food will be promulgated by the Environmental Protection Agency. Any other regulations under section 406 will be promulgated by FDA.

5. EPA will have primary responsibility for maintenance of an analytical reference standards repository of pesticides for which tolerances are established. FDA will transfer to EPA those samples which have been prepared for this purpose. Upon request, portions of these samples will be made available to the FDA and local enforcement authorities as needed for use in official analysis.

6. Each agency will appoint an individual and alternates who shall be responsible for interagency cooperation and coordination.

   a. These representatives, with staff support as desired, shall meet regularly on a mutually agreeable schedule to discuss program and policy coordination and to establish operating procedures between the agencies. Primary functions of the representatives are:

      i) To assure adherence to the general provisions of paragraphs 1-4 above, inclusive;

      ii) To promote mutual concurrence on chemical, toxicologic, and pharmacologic requirements for pesticide tolerances;

      iii) To provide for complete and timely exchange of information concerning proposed tolerances, administrative guidelines, methodology, research programs, monitoring, surveillance and enforcement programs, and legal action;

      iv) To provide that FDA will continue responsibility for agreements with States and foreign countries on surveillance and enforcement activities on pesticide residues in food;

      v) To provide that where the official U.S. delegate to international organizations is either EPA or FDA this will not automatically preclude representation by the other agency;

      vi) To provide that publication of FDA's Pesticide Analytical Manual for residues in foods and other environmental substrates will be continued as a joint FDA-EPA sponsorship under editoral management consisting of representatives of both agencies.

   b. Issues arising out of the above provisions which are not resolved after two regularly scheduled meetings shall be submitted through the organizational structure of each agency for resolution.

c. Agency representatives may propose additional agreements concerning these and other matters affecting interagency coordination and cooperation on the health aspects of pesticides and their residues in food and drugs. These proposals may be jointly approved by the Deputy Assistant Administrator for Pesticides Programs EPA, and the Commissioner of Food and Drugs, HEW.

For the Department of Health, Education and Welfare:

J. G. Veneman
Acting Secretary
June 17, 1971.

Charles C. Edwards,
Commissioner
May 11, 1971.

For the Environmental Protection Agency:

William D. Ruckelshaus
Administrator
September 4, 1971.

Effective date: This agreement became effective on November 10, 1971.

NOTE: This Memorandum of Agreement was published in the Federal Register of December 22, 1971 and was amended effective August 28, 1973. The amendments have been included in the document as printed above and consisted of:

1. the addition of paragraphs g. thru n. under Item 3 to further detail each agency's responsibilities on the regulation of drugs and pesticides and,

2. the substitution of the word "pesticide" for the term "economic poison" wherever it appears in the agreement in order to make the agreement compatible with the amendment of the FIFRA (86 Stat. 973).

## TASK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | | |
|---|---|---|---|
| PRODUCT REVIEWER: SGray | | RMB II | TEAM 34 |
| Description of Action: | | EPA File Symbol/Reg No. 71654-4 | |
| Decision No. 361039 | Submission No. S- 784963 | Fee for Service Action Code: | |
| FQPA Action Code: 352 | Non-FQPA Action Code: | PRIA FEE AMOUNT: | |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | September | 29 | 2005 |
| EPA PIN DATE | September | 30 | 2005 |
| REVIEWER ASSIGNED DATE | October | 04 | 2005 |
| DATE EXTENDED | | | |
| DATE DUE TO PM | | | |
| DATE DUE OUT OF AGENCY | | | 2005 |

| Type of Data: | PSB Product Chemistry | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure |
|---|---|---|---|---|---|---|---|

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM*

Notification

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only | | |
|---|---|---|---|
| Contractor: Arctic Slope | | Contract No.: 0411 | *ARCTIC SLOPE*/MANAGER |
| Draft Task: Signature _____ | _____ (Est. hrs) | Final Task: Signature _____ | 1.5 (Total hrs) |

C Reviewer's Comments:

| DATE FEE PAID: | RESPONSE CODE: 17 RESPONSE DATE: 10/24/05 |
|---|---|
| | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 26, 2005

Thomas C. McEntee
Product Registration Manager
Dupont Chemical Solutions Enterprise
Barley Mill Plaza
4417 Lancaster Plaza
Wilmington, DE 19805

Subject: Virkon® S
EPA Registration No. 71654-6
Application Date: September 29, 2005
EPA Received Date: September 30, 2005

Dear Mr. McEntee:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification**

- Alternate Brand Name "DuPont™ Virkon® Aquatic Disinfectant and Virucide"

**General Comments**

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

| CONCURRENCES | | | | | | | |
|---|---|---|---|---|---|---|---|
| SYMBOL | 7510C | | | | | | |
| SURNAME | A Heyward | | | | | | |
| DATE | 10-26-05 | | | | | | |

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

34

TRANSMITTAL LETTER

September 29, 2005

Document Processing Desk
Antimicrobials Division (7510C)
US Environmental Protection Agency
Office of Pesticide Programs
Mr. Adam Heyward (PM34)
Room 266A, Crystal Mall #2
1801 S. Bell Street
Arlington, VA 22202-4501

Reference: Virkon ® S
EPA Registration No. 71654-6

Dear Mr. Heyward,

Please find the attached application form 8570-1 for notification of the alternate brand name:

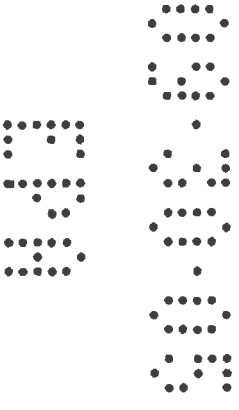
DuPont ™ Virkon ® Aquatic Disinfectant and Virucide

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
Dupont Chemical Solutions Enterprise
Barley Mill Plaza, P. O. Box 80023
4417 Lancaster Pike
Wilmington, DE 19805



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 71654-6 | Adam Heyward | [X] None [ ] Restricted |
| **4. Company/Product (Name)** | **PMS** | |
| Virkon (R) S | 34 | |

**5. Name and Address of Applicant** *(Include ZIP Code)*

E.I.du pont de Nemours & Company
Dupont Chemical Solutions Enterprise, P. O. Box 80023
Wilmington, DE 19880-0023

[ ] *Check if this is a new address*

**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand Name per PR Notice 98-10 DuPont (TM) Virkon (R) Aquatic Disinfectant and Virucide

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I furhter understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| [ ] Yes<br>[X] No | [ ] Yes<br>[ ] No | [ ] Yes<br>[ ] No | [ ] Metal<br>[X] Plastic<br>[ ] Glass<br>[ ] Paper<br>[ ] Other (Specify) _____ |
| * *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| [X] Label [ ] Container | 10 lb., 1lb., 9 oz. | [X] |

**6. Manner in Which Label is Affixed to Product** [x] Lithograph Paper glued Stenciled [ ] Other _____

## Section - IV

**1. Contact Point** *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Thomas C. McEntee | Product Registration Manager | 302 992 3771 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

**6. Date Application Received.** (Stamped)

| 2. Signature | 3. Title | 4. Typed Name | 5. Date |
|---|---|---|---|
| Thomas C. McEntee | Product Registration Manager | Thomas C. McEntee | Septemer 29, 2005 |

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

## RISK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | | |
|---|---|---|---|
| PRODUCT REVIEWER Sherri Gray | | | RMB II TEAM 34 |
| Description of Action: | | | EPA File Symbol/Reg No. 71654-6 |
| Decision No. 361432 | Submission No. 785551 | | Fee for Service Action Code: |
| FQPA Action Code: 332 | Non-FQPA Action Code: | | PRIA FEE AMOUNT: |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | October | 11 | 2005 |
| EPA PIN DATE | October | 13 | 2005 |
| REVIEWER ASSIGNED DATE | October | 17 | 2005 |
| DATE DUE FROM SCIENCE | | | |
| DATE DUE TO PM | November | 7 | 2005 |
| DATE DUE OUT OF AGENCY | | | |

| Type of Data: | PSB Product Chemistry | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure |
|---|---|---|---|---|---|---|---|

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM*

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only | |
|---|---|---|
| Contractor: Arctic Slope | Contract No.: 0411 | *ARCTIC SLOPE*/MANAGER |
| Draft Task: Signature _____ _____ (Est. hrs) | Final Task: Signature _____ 1.5 (Total hrs) | |

| C | Reviewer's Comments: |
|---|---|

| DATE FEE PAID: | RESPONSE CODE: 17 RESPONSE DATE: 10/24/05 |
|---|---|

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 26, 2005

Thomas C. McEntee
Product Registration Manager
Dupont Chemical Solutions Enterprise
Barley Mill Plaza
4417 Lancaster Plaza
Wilmington, DE 19805

Subject: Virkon® S
EPA Registration No. 71654-6
Application Date: October 11, 2005
EPA Received Date: October 13, 2005

Dear Mr. McEntee:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification**

- Alternate Brand Name "DuPont™ Trifectant® Broad Spectrum Disinfectant"

**General Comments**

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

| CONCURRENCES | | | | | | | |
|---|---|---|---|---|---|---|---|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | 10/26/05 | | | | | | |

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

DuPont Chemical Solutions Enterprise
P.O. Box 80023
Wilmington, DE 19880-0023

DuPont Chemical Solutions Enterprise

TRANSMITTAL LETTER

October 11, 2005

Document Processing Desk (NOTIF)
Antimicrobials Division (7510C)
US Environmental Protection Agency
Office of Pesticide Programs
Mr. Adam Heyward (PM34)
Room 266A, Crystal Mall #2
1801 S. Bell Street
Arlington, VA 22202-4501

Reference: Virkon ® S
EPA Registration No. 71654-6

Dear Mr. Heyward,

Please find the attached application form 8570-1 for notification of the alternate brand name:

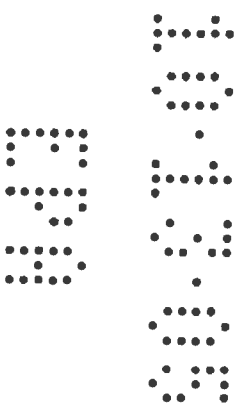
DuPont ™ trifectant ® Broad Spectrum Disinfectant

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
Dupont Chemical Solutions Enterprise
Barley Mill Plaza, P. O. Box 80023
4417 Lancaster Pike
Wilmington, DE 19805



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 71654-6 | Adam Heyward | [X] None [ ] Restricted |
| **4. Company/Product (Name)** | **PM#** | |
| Virkon (R) S | 34 | |

**5. Name and Address of Applicant** *(Include ZIP Code)*

E.I.du pont de Nemours & Company
Dupont Chemical Solutions Enterprise, P. O. Box 80023
Wilmington, DE 19880-0023

[ ] *Check if this is a new address*

**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand Name per PR Notice 98-10 DuPont (TM) trifectant (R) Broad Spectrum Disinfectant

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I furhter understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| [ ] Yes [X] No | [ ] Yes [ ] No | [ ] Yes [ ] No | [ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____ |
| *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| [X] Label [ ] Container | 10 lb., 1lb., 9 oz. | [X] |

**6. Manner in Which Label is Affixed to Product** [X] Lithograph Paper glued Stenciled [ ] Other _____

## Section - IV

**1. Contact Point** *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Thomas C. McEntee | Product Registration Manager | 302 992 3771 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

**6. Date Application Received** (Stamped)

| 2. Signature | 3. Title |
|---|---|
| Thomas C. McEntee | Product Registration Manager |
| **4. Typed Name** | **5. Date** |
| Thomas C. McEntee | October 11, 2005 |

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

## TASK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | | |
|---|---|---|---|
| PRODUCT REVIEWER: S Gray | | | RMB II TEAM 34 |
| Description of Action: | | | EPA File Symbol/Reg No. 71654-G |
| Decision No. 361040 | Submission No. S- 78467 | | Fee for Service Action Code: |
| FQPA Action Code: 332 | Non-FQPA Action Code: | | PRIA FEE AMOUNT: |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | September | 30 | 2005 |
| EPA PIN DATE | September | 30 | 2005 |
| REVIEWER ASSIGNED DATE | October | 04 | 2005 |
| DATE EXTENDED | | | |
| DATE DUE TO PM | | | |
| DATE DUE OUT OF AGENCY | | | 2005 |

| Type of Data: | PSB Product Chemistry | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure |
|---|---|---|---|---|---|---|---|

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM*

Notification

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only | | |
|---|---|---|---|
| Contractor: Arctic Slope | | Contract No.: 0411 | *ARCTIC SLOPE*/MANAGER |
| Draft Task: Signature _____ | _____ (Est. hrs) | Final Task: Signature _____ 1.5 (Total hrs) | |

C Reviewer's Comments:

| DATE FEE PAID: | RESPONSE CODE: 1 RESPONSE DATE: 10-26-05 |
|---|---|
| | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 26, 2005

Thomas C. McEntee
Product Registration Manager
Dupont Chemical Solutions Enterprise
Barley Mill Plaza
4417 Lancaster Plaza
Wilmington, DE 19805

Subject: Virkon® S
EPA Registration No. 71654-6
Application Date: September 30, 2005
EPA Received Date: October 3, 2005

Dear Mr. McEntee:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification**

- Alternate Brand Name "DuPont™ Virkon® VC Disinfectant and Virucide for Veterinary Use"

**General Comments**

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

| CONCURRENCES | | | | | | | |
|---|---|---|---|---|---|---|---|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | 10/26/05 | | | | | | |

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

34

TRANSMITTAL LETTER

September 30, 2005

Document Processing Desk (NOTIF)
Antimicrobials Division (7510C)
US Environmental Protection Agency
Office of Pesticide Programs
Mr. Adam Heyward (PM34)
Room 266A, Crystal Mall #2
1801 S. Bell Street
Arlington, VA 22202-4501

Reference: Virkon ® S
EPA Registration No. 71654-6

Dear Mr. Heyward,

Please find the attached application form 8570-1 for notification of the alternate brand name:

DuPont ™ Virkon ® VC Disinfectant and Virucide for Veterinary Use

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
Dupont Chemical Solutions Enterprise
Barley Mill Plaza, P. O. Box 80023
4417 Lancaster Pike
Wilmington, DE 19805

Please read instructions on reverse before completing form.

Form Approved. OMB No 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 71654-6 | Adam Heyward | [X] None [ ] Restricted |
| **4. Company/Product (Name)** | **PM#** | |
| Virkon (R) S | 34 | |

**5. Name and Address of Applicant** *(Include ZIP Code)*

E.I.du pont de Nemours & Company
Dupont Chemical Solutions Enterprise, P. O. Box 80023
Wilmington, DE 19880-0023

[ ] *Check if this is a new address*

**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in reponse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand Name per PR Notice 98-10 DuPont (TM) Virkon (R) VC Disinfectant and Virucide for Veterinary Use

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I furhter understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| [ ] Yes [X] No | [ ] Yes [ ] No | [ ] Yes [ ] No | [ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____ |
| *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| [X] Label [ ] Container | 10 lb., 1lb., 9 oz. | [X] |

**6. Manner in Which Label is Affixed to Product** [x] Lithograph Paper glued Stenciled [ ] Other _____

## Section - IV

**1. Contact Point** *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Thomas C. McEntee | Product Registration Manager | 302 992 3771 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

**6. Date Application Received** (Stamped)

| 2. Signature | 3. Title |
|---|---|
| Thomas C. McEntee | Product Registration Manager |
| **4. Typed Name** | **5. Date** |
| Thomas C. McEntee | Septemer 30, 2005 |

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

# TASK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | | |
|---|---|---|---|
| PRODUCT REVIEWER Sherrie Gray | | RMB II | TEAM 34 |
| Description of Action: | | EPA File Symbol/Reg No. 71654-6 | |
| Decision No. 359833 | Submission No. 782723 | Fee for Service Action Code: | |
| FQPA Action Code: 362 | Non-FQPA Action Code: | PRIA FEE AMOUNT:$ | |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | AUGUST | 02 | 2005 |
| EPA PIN DATE | AUGUST | 08 | 2005 |
| REVIEWER ASSIGNED DATE | AUGUST | 15 | 2005 |
| DATE DUE FROM SCIENCE | | | |
| DATE DUE TO PM | | | 2005 |
| DATE DUE OUT OF AGENCY | | | |

| Type of Data: | PSB Product Chemistry √ | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure |
|---|---|---|---|---|---|---|---|

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM*

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only | | |
|---|---|---|---|
| Contractor: Arctic Slope | | Contract No.: 0332 | *ARCTIC SLOPE*/MANAGER |
| Draft Task: Signature _____ | _____ (Est. hrs) | Final Task: Signature SG | 3 (Total hrs) |

C Reviewer's Comments:

| DATE FEE PAID: | RESPONSE CODE: 17 RESPONSE DATE: 10/20/05 |
|---|---|
| | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 26, 2005

Thomas C. McEntee
Product Registration Manager
Dupont Chemical Solutions Enterprise
Barley Mill Plaza
4417 Lancaster Plaza
Wilmington, DE 19805

Subject: Virkon® S
EPA Registration No. 71654-6
Application Date: August 2, 2005
EPA Received Date: August8, 2005

Dear Mr. McEntee:

The following amendment, submitted under connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FFIRA), as amended, is acceptable:

**Proposed Amendment**

- Submission of Certified Limits, Enforcement Analytical Method, Bulk Density, pH, and Oxidation/Reduction Studies

**General Comments**

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

| CONCURRENCES | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| SYMBOL | | | | | | | | |
| SURNAME | | | | | | | | |
| DATE | | | | | | | | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
**Antimicrobials Division**

**September 28, 2005**

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Virkon S**

**DP Barcode: D320694** **Reg. No. Or File Symbol: 71654-6**
**Manufacturing-use [ ]** OR **End-use Product [X]**

**TO:** Adam Heyward PM 34 / Sherri Gray, Team Reviewer
Regulatory Management Branch II
Antimicrobials Division (7510C)

**FROM:** Robert Turpin, Chemist R. T.
Product Science Branch, CT Team
Antimicrobials Division (7510C)

**THRU:** Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C) 9/29/05

**THRU:** Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

**Product Formulation**

| **Active Ingredient(s)** | **% by wt.** |
|---|---|
| Potassium peroxymonosulfate ..... | 21.41 |
| Sodium chloride ..... | 1.50 |

**BACKGROUND:** The registrant has submitted data in response to the Agency's request of November 10, 2004. Submitted are studies according to guidelines 830.1750, -1800, -7300, -7000, and –6314.

**FINDINGS:**

1. MRID #466175-01: The report contains a description and data responding to the requirements of OPPTS Test Guideline 830.1800. The test method, titration, and the resulting data are acceptable.

2. MRID #466175-02: The report contains data responding to the requirements of OPPTS Test Guidelines 830.6314, -7000, and –7300. The data indicated a slight reducing potential and no reaction to powdered iron. The pH was determined to be 2.10 @ 25° C, and the bulk density was 0.981 g/ml @ 24° C. The data are acceptable.

3. MRID #466175-03: The report contains data responding to the requirements OPPTS Test Guideline 830.1750. The data are acceptable.

4. The storage stability and corrosion characteristics studies are on-going and will be made available to the Agency upon completion.

**RECOMMENDATIONS: None.**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 9, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY
BMP 23/2161, PO Box 80023
WILMINGTON, DE 19880-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 08-AUG-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

DuPont Chemical Solutions Enterprise
P. O. Box 80023
Wilmington, DE 19880-0023

DUPONT

**466175-00**

DuPont Chemical Solutions Enterprise

TRANSMITTAL LETTER

August 2, 2005

Document Processing Desk
Antimicrobials Division (7510C)
US Environmental Protection Agency
Office of Pesticide Programs
Mr. Adam Heyward (PM34)
Room 266A, Crystal Mall #2
1801 S. Bell Street
Arlington, VA 22202-4501

Reference: Virkon ® S
EPA Registration No. 71654-6
(Previously EPA Reg. No. 62462-1)

Dear Mr. Heyward,

This letter and its attachments are in response to your November 10, 2004 letter. The following studies are attached:

830.1750 Certified Limits
830.1800 Enforcement Analytical Method
830.7300 Bulk Density
830.7000 pH
830.6314 Oxidation/Reduction

The following studies are in progress with completion dates in July 2006:

830.6317 Storage Stability
830.6329 Corrosion Characteristics

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com

*TRANSMITTAL DOCUMENT*

**Attention:**
Mr. Adam Heyward
Antimicrobials Division (7510C)
US Environmental Protection Agency
Office of Pesticide Programs
1801 S Bell Street
Arlington, VA 22202

**NAME AND ADDRESS OF SUBMITTER**
DuPont Chemical Solutions Enterprise
P. O. Box 80023
Wilmington, DE 19880-0023

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-
Response to US EPA Letter of November 10, 2004

**"Virkon® S"; EPA Registration No. 71654-6**

Transmittal Date: **August 2, 2005**

**Transmittal Material:**

| | | | |
|---|---|---|---|
| Volume 1 | Administrative Materials | | |
| | -Cover Letter | | 1 page |
| | -Application for Pesticide Registration (EPA Form 8570-1) | | 1 page |
| | -Transmittal Document | | this page |
| | -Data matrix (EPA Form 8570-35) | | 1 page |
| | -Memo: Case Consulting Labs to E. I. DuPont de Nemours and Company Initial Storage Stability and Corrosion Characteristics, OPPTS Test Guidelines, Series 830.6317 and 830.6320.;July 7, 2005 | | 3 pages |
| 46617501 | Volume 2 | Preliminary Analysis – Group A Product Properties OPPTS 830.1800 Study Title: "H26819 Enforcement Analytical Method" (7 pages) **H26891 is a synonym for Virkon S**; EPA Registration No. 71654-6 | |
| 46617502 | Volume 3 | Physical and Chemical Properties - OPPTS Group B OPPTS 830.6314, 803.7000 and 830.7300; Study Title: " Physical and Chemical Characteristics of H26820: Oxidation/Reduction: Chemical Incompatibility, pH, and Bulk Density" **H26820 is a synonym for Virkon S. EPA Reg. No. 72654-6** 7 pages | |
| 46617503 | **Volume 4** | Certified Limits; EPA Registration No. 71654-6; OPPTS 830.1750 (4 pages) | |

**********

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [X] Other

OPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 71654-6 | Adam Heyward | [X] None [ ] Restricted |
| **4. Company/Product (Name)** | **PM#** | |
| Virkon (R) S | 34 | |

**5. Name and Address of Applicant** *(Include ZIP Code)*

E.I.du pont de Nemours & Company
Dupont Chemical Solutions Enterprise, P. O. Box 80023
Wilmington, DE 19880-0023

[ ] *Check if this is a new address*

**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

## Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated Nov. 10, 2004
- [ ] Notification - Explain below.
- [ ] Final printed labels in reponse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| [ ] Yes [X] No | [ ] Yes [ ] No | [X] Yes [ ] No | [ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____ |
| *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| [X] Label [ ] Container | 10 lb., 1lb., 9 oz. | [X] |

**6. Manner in Which Label is Affixed to Product** [x] Lithograph Paper glued Stenciled [ ] Other _____

## Section - IV

**1. Contact Point** *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Thomas C. McEntee | Product Registration Manager | 302 992 3771 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

**6. Date Application Received** (Stamped)

| 2. Signature | 3. Title |
|---|---|
| Thomas C McEntee | Product Registration Manager |
| **4. Typed Name** | **5. Date** |
| Thomas C. McEntee | August 2, 2005 |

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

# *Case Consulting Laboratories, Inc.*

622 Route Ten
Whippany, New Jersey 07981
Tel. 973-428-9666
Fax. 973-887-4419
E-Mail: case@case-labs.com

July 7, 2005

To: E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprises
P.O. Box 80023
Wilmington, DE 19880-0023

Attention: Thomas C. McEntee
Registration Manager

From: David J. Sinning
Study Director

CCL Study No.: 3280-05

Sponsor Study No.: DuPont-17476

Test Substance: H26820

Synonym: Virkon S

Lot No.: 19861

Active Ingredient: Potassium peroxymonosulfate, 50% (10.4% Available Oxidant as $Cl_2$)

Subject: Initial Storage Stability and Corrosion Characteristics, OPPTS Test Guidelines, Series 830, Product Properties: 830.6317 and 830.6320

OBJECTIVE

To determine the storage stability and corrosion characteristics of one lot of H26820.

TEST METHOD

830.6317: Storage Stability

The test was conducted with the test substance in order to establish an initial value. The test substance will also be evaluated after 3, 6 9 and 12 months at room temperature in contact with its commercial packaging material (high density polyethylene). All details of the method used will be documented in the raw data and will be presented in the Final Report which will be submitted upon completion of the 12 month interval.

Physical Changes

At the 3, 6, 9 and 12 month storage stability intervals, the test substance will be examined for any physical changes such as phase separation or clumping and, in particular, any changes that would interfere with the usefulness or safe handling of the product if used according to label directions.

830.6320: Corrosion Characteristics

At the 12 month storage stability intervals, the commercial packaging material (high density polyethylene) used for the storage stability test will be visually inspected. Any changes in the material will be noted and recorded.

RESULTS

Test Substance: H26820
Lot No.: 19861

Guideline

830.6317: Storage Stability

% Available Oxidant:

| Interval | Replicate 1 | Replicate 2 | Average |
|---|---|---|---|
| • Initial | 10.36 | 10.31 | 10.33 |
| • After 3 Months at Room Temperature | To be reported upon completion | | |
| • After 6 Months at Room Temperature | To be reported upon completion | | |
| • After 9 Months at Room Temperature | To be reported upon completion | | |
| • After 12 Months at Room Temperature | To be reported upon completion | | |

Physical Changes:

| Interval | Observation |
|---|---|
| • After 3 Months at Room Temperature | To be reported upon completion |
| • After 6 Months at Room Temperature | To be reported upon completion |
| • After 9 Months at Room Temperature | To be reported upon completion |
| • After 12 Months at Room Temperature | To be reported upon completion |

RESULTS CONT'D.

Test Substance: H26820
Lot No.: 19861

Guideline

830.6320: Corrosion Characteristics:

| Interval | Observation |
|---|---|
| • After 12 Months at Room Temperature | To be reported upon completion |

Respectfully submitted,

David J. Sinning
Study Director

CASE CONSULTING LABORATORIES, INC.

ra

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

| | | |
|---|---|---|
| Date August 2, 2005 | EPA Reg No./File Symbol 71654-6 | Page 1 of 1 |
| Applicant's/Registrant's Name & Address E. I. du Pont de Nemours and Company<br>P.O. box 80023 Wilmington, De 19880-0023 | Product Virkon (R) S | |

Ingredient potassium peroxymonosulfate

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.1750 | Certified Limits | | E.I du Pont de Nemours | | Attached |
| 830.1800 | Enforcement Analytical Method | | E.I du Pont de Nemours | | Attached |
| 830.7300 | Bulk Density | | E.I du Pont de Nemours | | Attached |
| 830.7000 | pH | | E.I du Pont de Nemours | | Attached |
| 830.6314 | Oxidation/Reduction | | E.I du Pont de Nemours | | Attached |
| 830.6315 | Flammability | | Not Applicable to powder 6315(b)(ii) | | |
| 830.6321 | Dielectric Breakdown Voltage | | Not Applicable to powder 6321(b)(1) | | |
| | | | | | |
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| | | |
|---|---|---|
| Signature Thomas C. McEntee | Name and Title Thomas C. McEntee, Product Registration Manager | Date Aug. 2, 2005 |

EPA Form 8570-35 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460 Do not send the form to this address.

DATA MATRIX

| Date August 2, 2005 | EPA Reg No./File Symbol 71654-6 | Page 1 of 1 |
|---|---|---|
| Applicant's/Registrant's Name & Address E. I. du Pont de Nemours and Company P.O. box 80023 Wilmington, De 19880-0023 | Product Virkon (R) S | |

Ingredient [redacted]

| Submitter | Status | Note |
|---|---|---|
| E.I du Pont de Nemours | | |
| E.I du Pont de Nemours | | |
| E.I du Pont de Nemours | | |
| E.I du Pont de Nemours | | |
| E.I du Pont de Nemours | | |
| Not Applicable to powder 6315(b)(i | | |
| Not Applicable to powder 6321(b)(1) | | |
| | | |
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| | | |
| | | |
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| | | |

| Signature | Name and Title Thomas C. McEntee, Product Registration Manager | Date Aug. 2 2005 |
|---|---|---|

EPA Form 8570-35 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

FQPA FQPA

# TASK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager |
|---|---|

| | |
|---|---|
| PRODUCT REVIEWER: *SGRAY* | RMB II TEAM 34 |
| Description of Action: | EPA File Symbol/Reg No. 71654-6 |
| Decision No. 354866 Submission No. 175868 | Fee for Service Action Code: |
| FQPA Action Code: 362 Non-FQPA Action Code: | Fee for Service Fee: $ |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | MARCH | 04 | 2005 |
| EPA PIN DATE | MARCH | 10 | 2005 |
| REVIEWER ASSIGNED DATE | MARCH | 14 | 2005 |
| E DUE FROM SCIENCE | MAY | 09 | 2005 |
| DATE DUE TO PM | JUNE | 01 | 2005 |
| DATE DUE OUT OF AGENCY | JUNE | 08 | |

| Type of Data: | PSB Product Chemistry ☒ | PSB Acute Toxicology ☐ | PSB Efficacy ☐ | RASSB Environmental Fate ☐ | RASSB Ecological Effects ☐ | RASSB Chronic Toxicology ☐ | RASSB Exposure ☐ |
|---|---|---|---|---|---|---|---|

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.*

ATTACHMENTS: ☒-LABELING ☒-CSF(S) ☐-DATA ☐-OTHERS

| B | For Arctic Slope Contract Only |
|---|---|

| | | |
|---|---|---|
| Contractor: Arctic Slope | Contract No.: 0332 | *ARCTIC SLOPE/MANAGER* |
| Draft Task: Signature _____ _____ (Est. hrs) | Final Task: Signature DS _____ 3 (Total hrs) | |

| C | Reviewer's Comments: |
|---|---|

DATE FEE PAID: N/A RESPONSE CODE: 17 RESPONSE DATE: 4/7/05

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 7, 2005

Thomas C. McEntee
Regulatory Manager
E.I. duPont de Nemours and Company
DuPont Chemical Solutions Enterprise
P.O. Box 80023
Wilmington, DE 19880-0023

Subject: Virkon® S
EPA Registration Number 71654-6
Application Date: March 4, 2005
EPA Received Date: March 10, 2005

Dear Mr. McEntee:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

**Proposed Amendment**

- Revised Alternate Confidential Statement of Formula (see CSF dated 3/4/05)

**General Comments**

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

| CONCURRENCES | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| SYMBOL | 7510C | | | | | | | |
| SURNAME | AHeyward | | | | | | | |
| DATE | 6/7/05 | | | | | | | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION PESTICIDES
AND TOXIC SUBSTANCES
**Antimicrobials Division**

**March 28, 2005**

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Virkon S**

**DP Barcode: D314453** **Reg. No. Or File Symbol: 71654-6**
**Manufacturing-use [ ]** OR **End-use Product [X]**

**TO:** Adam Heyward PM 34 / Sherri Gray, Team Reviewer
Regulatory Management Branch II
Antimicrobials Division (7510C)

**FROM:** Robert A. Turpin, Chemist R. T.
Product Science Branch, CT Team
Antimicrobials Division (7510C)

**THRU:** Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C) 3/29/05

**THRU:** Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

**Product Formulation**

| **Active Ingredient(s)** | **% by wt.** |
|---|---|
| Potassium peroxymonosulfate ..... | 21.41 |
| Sodium chloride ..... | 1.50 |

**BACKGROUND:** The registrant has submitted an amendment to its registration reducing the nominal concentration of dye in the formulation and increasing the concentration of the [redacted] by a corresponding amount. The registrant is also notifying the Agency of changes of two suppliers of inert ingredients and correcting the address of the supplier of colorant.

**FINDINGS:**

1. The Confidential Statement of Formula of the subject product, dated March 4, 2005, with the reduced dye content is acceptable to the Agency.

2. The substitute suppliers of inert materials are acceptable.

**RECOMMENDATIONS: None.**

34

DuPont Chemical Solutions Enterprise
P. O. Box 80023
Wilmington, DE 19880-0023

DuPont Chemical Solutions Enterprise

DELIVERED BY COURIER

March 4, 2005

Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Attn: Adam Heyward (PM34)
Room 266A, Crystal Mall2
1801 S. Bell Street
Arlington, VA 22202-4501

**SUBJECT: Minor Formulation Change for Accelerated Review per PR Notice 98-10:**

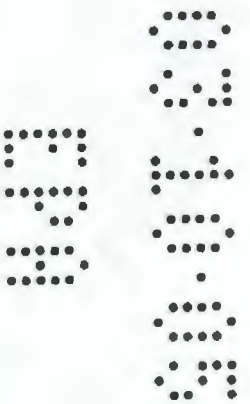
**Virkon® S (EPA Registration Number 71654-6)**

Dear Mr. Heyward:

Consistent with PR Notice 98-10, E.I. du Pont de Nemours and Company wishes make a minor formulation amendment for Virkon® S (EPA Reg Number 71654-6). This amendment is being submitted to support alternate formulations of Virkon® S with reduced levels of colorant.

The CSF being submitted is for an alternate tablet formulation with a nominal level of [redacted] dye the only change from an existing approved formulation is the level of colorant & the corresponding slight increase in the [redacted] These minimal formulation changes do not change the product's acute toxicity category or physical chemical characteristics nor does it affect the product's efficacy.

By way of this letter, and also in accordance with PR Notice 98-10, we are also notifying the Agency of changes to the supplier of 2 inert ingredients [redacted] and correction to the address of our colorant supplier. These corrections are reflected in the attached CSF and are summarized below:



*Inert ingredient information may be entitled to confidential treatment*

| Component | Supplier Name/Address |
|---|---|
| [redacted] | |

Included with this amendment are:

- one (1) copy of the application form (EPA form 8570-1)
- one (1) copy of the CSF for the existing formulation
- two (2) copies of the CSF for the proposed formulation (dated March 4, 2005)

I would appreciate your prompt review of these alternate formulations. Please contact me by phone at (302)-992-3771 or by email at thomas.c.mcentee@usa.dupont.com if additional information is needed.

Sincerely,

Thomas C. McEntee
Regulatory Manager
DuPont Chemical Solutions Enterprise

*Please read instructions on reverse before completing form.* Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA — United States Environmental Protection Agency, Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

QPP Identifier Number

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 71654-6 | Adam Heyward | ☒ None ☐ Restricted |
| **4. Company/Product (Name)** Virkon(r) S | **PM#** 34 | |

**5. Name and Address of Applicant** *(Include ZIP Code)*
E. I. du Pont de Nemours & Company
DuPont Chemical Solutions Enterprise, P.O. Box 80023
Wilmington, DE 19880-0023 Attn: Bonnie J. Bieber

☐ *Check if this is a new address*

**6. Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

## Section - II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)
Accelerated review of minor formulation amendment per PR Notice 98-10. Fast track action - non-fee.

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes* ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____ |
| * *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☐ Label ☐ Container | | ☐ On Label ☐ On Labeling accompanying product |

**6. Manner in Which Label Is Affixed to Product** ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

## Section - IV

**1. Contact Point** *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Thomas C. McEntee | Regulatory Manager | 302-992-3771 |

### Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| 2. Signature | 3. Title | 6. Date Application Received (Stamped) |
|---|---|---|
| Thomas C. McEntee | Regulatory Manager | |
| **4. Typed Name** Thomas C. McEntee | **5. Date** March 4, 2005 | |

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

5B2-2

Please Read All Instructions Before Completing this Form *(Form must be typed)* Form Approved. OMB. No. 2070-0044

United States
**Environmental Protection Agency**
Office of Pesticide Programs (7505C)
Washington, DC 20460

EPA

Virkon base

# Notice of Supplemental Distribution of a Registered Pesticide Product

## *Instructions*

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

| EPA Registration Number of Product | Distributor Company Number |
|---|---|
| 71654-6 | 3134 |

**Note: Do not submit distributor product labels**

| Name of Registered Product *(basic product name accepted by EPA)* | Distributor Product Name |
|---|---|
| Virkon S | trifectant Broad Spectrum Disinfectant |

Name and Address of Distributor *(Type; include ZIP code)*

Vetoquinol USA Inc.
101 Lincoln Avenue
Buena, NJ 08310

## *Read All Conditions Before Signing*

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

### Distributor

*We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.*

Signature and Title of Distributor: ERIC I. LINN DVM, MPH Director Regulatory Compliance

Date: 24 Jan 05

### Registrant

*I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.*

Signature and Title of Registrant: Prod. Reg Mgr.

Date: 1/28/05

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. White - EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 11, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

**MEMORANDUM:**

**SUBJECT:** Screen Adverse Data [FIFRA 6(a)(2)] submission for Virkon® S, EPA Reg. No. 71654-6 Containing Sodium chloride and Potassium peroxymonosulfate

**TO:** Adam Heyward, Product Manager, Team 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

**FROM:** Srinivas Gowda, Microbiologist/Chemist Srinivas Gowda 1/11/05
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

**THRU:** Siroos Mostaghimi, Acting Team Leader, Team One Siroos - Mostaghimi
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Norm Cook, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

**DP Barcode:** D311802
**Decision #:** 352289
**Case Type:** Adverse Data 6(a)(2)
**PC Codes:** 013905 & 063604
**Chemical Names:**
Sodium Chloride
Potassium peroxymonosulfate

**EPA Reg. No.:** 71654-6
**MRID No.:** 463493-01
**Data Submitter:** DuPont Chemical
**CAS#:** 7647-14-5 (Sodium Chloride)
10058-23-8 (Potassium peroxymonosulfate)

**INTRODUCTION:**

DuPont Chemical Solutions Enterprises, has submitted Adverse Data (Chronic Trout Study) in Accordance with FIFRA Section 6(a)(2) for Virkon® S (EPA Reg. No. 71654-6). 6(a)(2) Coordinator, Sharon Carlisle, requests RASSB to screen and make a determination whether the package needs to be expedited quickly as a 6(a)(2) submission. The submitted adverse data (Chronic Trout Study) has undergone review by Srinivas Gowda of Antimicrobials Division's Risk Assessment and Science Support Branch.

**RECOMMENDATIONS:**

The submitted Adverse Data (Chronic Trout Study) under the MRID No. 463493-01 does not qualify as a 6(a)(2) submission. Risk Assessment and Science Support Branch recommends that the Chronic Trout Study for Virkon® S, EPA Reg. No. 71654-6, must be rerouted to RASSB for review under a miscellaneous (400) PRAT Code and revised due date.

DP #: (311802) Decision #: 352289

# DATA PACKAGE BEAN SHEET

**Date: 14-Jan-2005**



## * * * Registration Information * * *

Registration: 71654-6 - VIRKON S

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 34 - Adam Heyward - (703) 308-6422 Room# CM-2 308B

Risk Manager Reviewer: Sharon Carlisle SCARLISL

Sent Date: 29-Dec-2004 Calculated Due Date: 08-Nov-2004 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (405) ADVERSE DATA (6A2);

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxymonosulfate(20.4%)

## * * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 29-Dec-2004 Due Back:

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxymonosulfate

DP Title:

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #:

| | Assigned To | Date In | Date Out | | |
|---|---|---|---|---|---|
| Organization: | AD / RASSB | 29-Dec-2004 | 14-Jan-2005 | Administrative Due Date: | 23-Jan-2005 |
| Team Name: | RASSB1 | 29-Dec-2004 | 14-Jan-2005 | Negotiated Due Date: | |
| [redacted]wer Name: | Gowda, Srinivas | 29-Dec-2004 | 14-Jan-2005 | Projected Completion Date: | |
| Contractor Name: | | | | | |

## * * * Studies Sent for Review * * *

No Studies

## * * * Additional Data Package for this Decision * * *

No Additional Data Packages

## * * * Data Package Instructions * * *

RASSB: The attached data MRID# 46349301 is being submitted for a 6(a)(2) screening

DuPont Chemical Solutions Enterprise
P.O. Box 80023
Wilmington, DE 19880-0023

DuPont Chemical Solutions Enterprise

**DELIVERED BY COURIER**

August 24, 2004

Document Processing Desk - 6(a)(2)
Office of Pesticide Programs(7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 S. Bell St.
Arlington, VA 22202-4501

**SUBJECT: Information Submitted In Accordance with FIFRA Section 6(a)(2)**
**Report of a study with Virkon® S (EPA Reg # 62432-1)**

To Whom It May Concern:

Antec International has recently completed a chronic trout study with Virkon® S (EPA Reg # 62432-1). This research study was conducted to support non-US use patterns for this product; it was not conducted in accordance with OPPTS guidelines, nor was it conducted under GLP.

This ecological study appears to be reportable in accordance with 40 CFR. 159.165 (b). In this study, newly hatched trout were exposed to nominal concentrations of 0, 2, 4, 6, or 8 ppm Virkon® S in a flow-through system for a period of 100 days. Transient effects were seen on growth during the first feeding stage at 4 ppm, and on mortality and growth at treatment levels of 6 and 8 ppm. There were no adverse effects noted at 2 ppm. There were no significant histological differences between the outperforming fish at 4 ppm and controls, nor between any exposed fish and controls after first feeding stage was completed.

Antec International considers the entire contents of this letter to be subject to protection afforded under FIFRA Section 10(g). Disclosure of this information may be made only in accordance with that Section.

Please call me at 302/892-8268 if you have any questions.

Sincerely,

Bcnj R for Nancy B. Lomax

Nancy B. Lomax
Regulatory Manager &
US agent, Antec International

cc: Adam Heyward, PM# 34
cc: Mark Squire, Chief Chemist, Antec International

## DATA TRANSMITTAL DOCUMENT

Information Submitted In Accordance with FIFRA Section 6(a)(2) - Report of a study with Virkon® S (EPA Reg # 62432-1)

Antec International Ltd.
Sudbury, Suffolk, CO10 2XD
England

**Regulatory Action in Support of Which this Package is Submitted:**

Information Submitted In Accordance with FIFRA Section 6(a)(2) - Report of a study with Virkon® S (EPA Reg # 62432-1)

**Transmittal Date: August 24, 2004**

**List of Submitted Studies:**

| Data Requirement | Doc Number | Study Title | MRID |
|---|---|---|---|
| none | DCSE-2003-008 | Chronic Toxicity of Continuous Exposure to 'Virkon S for Aquaculture' to Rainbow Trout (*Oncorhynchus mykiss*) | 46348301 |

**Submitted by:** Nancy B Lomax **Date:** Aug 26 2004

Nancy B. Lomax
Regulatory Manager and Agent for Antec International Ltd.

**Telephone:** 302-892-8268

**Company Name:** Antec International Ltd.

Versar inc.

**MEMORANDUM**

**TO:** Srinivas Gowda

cc: Wanda Jakob
Pat Wood
11.0248.4000.002.05

**FROM:** Traci Brody / Amanda Jacob

**DATE:** February 24, 2005

**SUBJECT:** Data Evaluation Report for Sodium Chloride and Potassium Peroxymonosulfate (Virkon S for Aquaculture)
(Action No., GOW-07-III TAF 2-5-22)

---

Attached is a Data Evaluation Report (DER) for Sodium Chloride and Potassium Peroxymonosulfate (Virkon S for Aquaculture). The DER evaluates the chronic toxicity of continuous exposure to 'Virkon S for Aquaculture' to rainbow trout (*Oncorhynchus mykiss*) (MRID 463493-01). This study was not conducted in compliance with U.S. EPA FIFRA (40 CFR part 160) since it was conducted to support non-U.S. product uses. The DER was prepared based on the harmonized OPPTS Test Guideline 850.1400 for reviewing purposes, as the scope of the study is similar to that required by this guideline.

Please give us a call if you have any questions.

# DATA EVALUATION RECORD

**Sodium Chloride and Potassium Peroxymonosulfate**
**(Virkon S for Aquaculture)**

**Study Type: Fish Early Life Stage Toxicity Test**
**Guideline OPPTS 850.1400**

**Prepared for:**

**Antimicrobials Division**
**Office of Pesticide Programs**
**U.S. Environmental Protection Agency**
**1801 South Bell Street**
**Arlington, Virginia 22202**

**Prepared by:**

**Versar, Inc.**
**6850 Versar Center**
**P.O. Box 1549**
**Springfield, VA 22151**

**February 24, 2005**

**Contract Number: 68-W-01-036**
**Work Assignment No.: 0248.4000.002.05, TAF 2-5-22, Action No. GOW-07-III**
**EPA Work Assignment Manager: Srinivas Gowda**

# DATA EVALUATION RECORD
# FISH EARLY LIFE STAGE TOXICITY TEST
# GUIDELINE OPPTS 850.1400

1. **CHEMICAL:** Sodium Chloride and Potassium Peroxymonosulfate **PC Code No.:**

2. **TEST MATERIAL:** Virkon S for Aquaculture **Purity:** Not reported.

3. **CITATION**

| | |
|---|---|
| Authors: | Ronald W. Hardy<br>Ronald J. Roberts |
| Title: | Chronic Toxicity of Continuous Exposure to 'Virkon S for Aquaculture' to Rainbow Trout (*Oncorhynchus mykiss*) |
| Study Completion Date: | July 28, 2004 |
| Laboratory: | University of Idaho<br>Hagerman Fish Culture Experiment Station<br>3059F National Fish Hatchery Road<br>Hagerman, ID 83332 |
| Sponsor: | Antec Dupont |
| Laboratory Report ID: | DCSE-2004-001 |
| MRID No.: | 463493-01 |

4. **REVIEWED BY:**

**Signature:** **Date:**

5. **APPROVED BY:**

**Signature:** **Date:**

6. **STUDY PARAMETERS**

| | |
|---|---|
| **Scientific Name of Test Organism:** | *Oncorhynchus mykiss* |
| **Age of Test Organism:** | Newly hatched |
| **Definitive Test Duration:** | 100 days (then a 21 day remission and exposure for an additional 67 days, final sampling at 188 days) |
| **Study Method:** | Flow-through |
| **Type of Concentrations:** | Nominal |

7. **CONCLUSIONS**

**Results Synopsis:** At first feeding:

2 ppm - No mortality
4 ppm - NOEC
6 ppm - LC50
8 ppm - Lethal level

**Verified Results Synopsis:** Raw data were not reported in the study to verify.

## 8. ADEQUACY OF THE STUDY

**A. Classification:**

**B. Rationale:**

**C. Repairability:**

## 9. GUIDELINE DEVIATIONS:

The following guideline deviations were based on the EPA OPPTS Guideline 850.1400. However, it should be noted that this study was not conducted in compliance with U.S. EPA FIFRA (40 CFR part 160) since it was conducted to support non-U.S. product uses.

- The source of the fish used in the study was not reported.
- The post-hatch timing of the first feeding was not reported and the specifics on the amount of food based on percent body weight per day were not provided.
- The maintenance of the temperature and the frequency of the tank temperature monitoring was not reported.
- The study reported that the photoperiod was constant at 14 hours light/10 hours darkness. The guidelines recommend subdued lighting throughout the test and a 12/16 hour photoperiod.
- Chemical analysis of the tank water was not reported.
- Virkon S for Aquaculture was tested at four concentrations. The guidelines recommended utilizing five concentrations spaced by a constant factor for testing purposes.
- The study author did not report any monitoring of the test substance concentration or the flow rate throughout the study period.
- All fish were newly hatched prior to the initiation of the test; however, the exact age of the fish and the handling of the embryos and larvae were not provided.
- Hatching and post-hatching success were not reported.
- Six fish were sampled and fixed for histology examination of all organs routinely at 50 days, 100 days. The guidelines specify that fish should only be removed from the tanks upon death.
- The study author did not include any record of the fish behavior and did not report if the length of the fish were monitored/measured.
- The test material was supplied by Antec Dupont; however, no additional information regarding the test material (lot number, chemical/physical properties) were provided.
- A Quality Assurance Statement and the start date of the study were not provided.
- No raw data were provided for statistical method validation.

## 10. SUBMISSION PURPOSE: Registration

## 11. MATERIALS AND METHODS

### A. Test Organisms

| Guideline Criteria | Reported Information |
|---|---|
| **Species:**<br>• Recommended freshwater - rainbow trout (*Oncorhynchus mykiss*), fathead minnow (*Pimephales promelas*), zebra fish (*Danio rerio*), ricefish (*Oryzias latipes*)<br>• Recommended saltwater - sheepshead minnow (*Cyprinodon variegatus*)<br>• Examples of other well documented species listed in guidelines | • Commercial rainbow trout sac fry (*Oncorhynchus mykiss*) were used in the study (pp. 6 and 13). |
| **Source of organisms:** | • The source of the fish were not reported. |
| **Feeding:**<br>• Time to first feeding<br>Rainbow trout – 19 days post-hatch<br>Fathead minnow -- within 2 days of hatching<br>Zebra fish -- 6-7 days after spawning<br>Ricefish – within 24 hrs of hatch/swim-up<br>Sheepshead minnow -- within 24 hrs of hatch/swim-up<br>• Brood Fish Food Requirements<br>Rainbow trout – trout food<br>Fathead minnow – frozen brine shrimp<br>Zebra fish – brine shrimp nauplii, flake food<br>Ricefish – flake food<br>Sheepshead minnow – frozen brine shrimp or flake food<br>• Newly Hatched Larvae Food Requirements<br>Rainbow trout – does not require food<br>Fathead minnow -- brine shrimp nauplii, newly hatched<br>Zebra fish – protozoa (filtered from mixed culture), protein (granules from fermentation process)<br>Ricefish – brine shrimp nauplii, flake food (or protozoa or rotifers)<br>Sheepshead minnow -- brine shrimp nauplii<br>• Juveniles Food Requirements<br>Rainbow trout – trout starter/4% body weight per day/2-4 feeds per day<br>Fathead minnow -- brine shrimp nauplii/ad | • The rainbow trout fry were referred to as newly hatched at the time of exposure; however, the post-hatch timing of the first feeding was not reported (p. 12).<br>• Fish were fed commercial pellets (Silver Cup Feeds, Nelson and Sons, Inc., Salt Lake City, UT) to apparent satiation (pp. 6 and 13).<br>• Fry were fed 10x per day and decreased to 3x per day by the end of the trial in accordance with normal trout hatchery practice (p. 13).<br>• Specifics on percent body weight per day were not provided. |

| Guideline Criteria | Reported Information |
|---|---|
| libitum<br>Zebra fish -- brine shrimp nauplii<br>Ricefish – brine shrimp nauplii or flake food or rotifers/brine shrimp once daily; flake food twice daily or flake food and rotifers once daily<br>Sheepshead minnow -- brine shrimp nauplii/2-3 feeds per day<br><br>*Other well documented fish species requirements listed in guidelines. | |

**B. Test System**

| Guideline Criteria | Reported Information |
|---|---|
| **Temperature:**<br>• Must not differ by more than ± 1.5°C between test chambers or between successive days<br>• Measured in all test chambers weekly and preferably continuously in at least one vessel<br>• Specific test species requirements (°C):<br>Rainbow trout – 10 ± 2 for embryos; 12 ± 2 for larvae and juvenile fish[1]<br>Fathead minnow -- 25 ± 2<br>Zebra fish – 25 ± 2<br>Ricefish -- 24 ± 1; 23 ± 2 for larvae and juvenile fish; this supercedes the requirement for temperature control given earlier on in the test<br>Sheepshead minnow -- 25 ± 2<br><br>[1]the particular strain of rainbow trout may necessitate the use of other temperatures; brood stock must be held at the same temperature as that to be used for the eggs<br>*Other well documented fish species requirements listed in guidelines. | • It was reported that the tanks were maintained at a constant temperature of 14.5°C (p. 6, 13).<br><br>• The maintenance of the temperature and the frequency of the tank temperature monitoring was not reported. |
| **Salinity:**<br>• Sheepshead minnow – should be at 15-30; for any given test this shall be performed to ± 2%<br>• Should be measured in all vessels weekly | • All of the tanks contained spring water. Salinity was not reported. |

| Guideline Criteria | Reported Information |
|---|---|
| **Photoperiod:**<br>• Rainbow trout – darkness for larvae until one week after hatching except when they are being inspected, then subdued lighting throughout test (12-16 hr photoperiod)<br>• Fathead minnow – 16 hr<br>• Zebra fish – 12-16 hr; for any given test conditions, light regime should be constant<br>• Ricefish – 12-16 hr; for any given test conditions, light regime should be constant<br>• Sheepshead minnow – 12-16 hr; for any given test conditions, light regime should be constant<br>• *Other well documented fish species requirements listed in guidelines. | • The photoperiod was constant at 14 hours light/10 hours darkness controlled by timers and fluorescent lights (p. 6). |
| **Test Chambers:**<br>• Any glass, stainless steel, or other chemically inert vessel can be used | • The test chambers were 15 x 150 L fiberglass tanks (p. 6). |
| **Handling of embryos and larvae:**<br>• Initially, may be exposed within main vessel in smaller glass or stainless steel vessels, fitted with mesh sides or ends to permit flow of test solution<br>• May be suspended from an arm arranged to move vessel up and down to induce non-turbulent flow; organisms must always be submerged<br>• Egg containers, grids or mesh should be removed after larvae hatch, except mesh should be retained to prevent escape of fish<br>• If need to transfer larvae, should not be exposed to air and nets should not be used to release fish from egg containers<br>• Post-hatch transfer time requirements:<br>Rainbow trout – 14-16 days post-hatch<br>Fathead minnow – once hatching is 90%<br>Zebra fish – not necessary<br>Ricefish – from hatch to swim-up<br>Sheepshead minnow – not applicable<br><br>*Other well documented species requirements listed in guidelines. | • All fish utilized in this study were hatched prior to the initiation of the testing period. |

| Guideline Criteria | Reported Information |
|---|---|
| **Loading of Fish**:<br>• Randomly distributed<br>• At least 60 eggs, divided equally between at least 2 replicate test chambers per concentration<br>• Loading rate low enough to allow oxygen concentration of at least 60% saturation maintained without aeration<br>• For flow through test, loading rate not to exceed 0.5g/L/24 hr and 5g/L of solution at any time | • Initially, 500 newly hatched fish were placed in each of the triplicate tanks. The number of fish was reduced to 250 fish at 1 g weight, and a further reduction to 100 fish per tank was made when fish reached 10 g (300 fish total per treatment) (p. 6). |
| **Dissolved Oxygen:**<br>• Should be measured in all vessels weekly<br>• Between 60 and 100% saturation | • Dissolved oxygen data were not reported. |
| **pH:**<br>• Should be measured in all vessels at beginning and end of test | • pH values were not reported. |
| **Water:**<br>• Any water in which test species shows control survival at least as good as that listed below (see Survival Criteria)<br>• Dilution water samples should be taken at intervals (e.g., every 3 months) and analyzed for heavy metals, pesticides, total organic carbon, major anions and cations, and suspended solids<br>• Acceptable chemical characteristics of dilution water: particulate matter - <20 mg/L, total organic carbon - <2 mg/L, un-ionized ammonia - <1$\mu$g/L, residual chlorine - <10$\mu$g/L, total organophosphorus pesticides - <50 ng/L, total organochlorine pesticides plus PCBs - <50ng/L, total organic chlorine - <25ng/L | • The tanks were supplied with spring water (14.5°C) at 4 L/min to the yolk sac fry, 8 L/min at swim up, and 16 L/min. at first feeding (p. 13).<br>• Chemical analysis of the tank water was not reported. |

| Guideline Criteria | Reported Information |
|---|---|
| **Renewal:**<br>• For flow through systems, require system which continually dispenses and dilutes a stock solution of the test substance<br>• Flow rates of stock solution and dilution water should be checked at intervals during the test and should not vary by more than 10% throughout the test<br>• A flow rate equivalent to at least 5 test chamber volumes per 24 hr has found to be suitable<br>• For semi-static technique, two different renewal systems may be followed: (1) new test solutions prepared in clean vessels and surviving eggs and larvae gently transferred into new vessels or (2) test organisms are retained in test vessels while a proportion (at least 2/3) of the test water is changed | • Fish were exposed to four levels of Virkon S for Aquaculture, supplied by peristaltic dosing pumps. The chemical was prepared at an initial dilution of 1:50 and supplied at an appropriate rate, by pump, so as to supply a final concentration of 2 ppm, 4 ppm, 6 ppm, and 8 ppm in the incoming water of the test tanks (p. 13).<br>• The study author did not report any periodic monitoring of the flow rate throughout the study.<br>• The flow through rate was 16 L/min. at first feeding (p. 13). |

C. Test Design

| Guideline Criteria | Reported Information |
|---|---|
| **Doses**<br>• Five concentrations of test substance spaced by a constant factor not exceeding 3.2<br>• Use of fewer than five concentrations, for example in limit tests, and a narrower concentration interval may be appropriate; justification required<br>• When solubilizing agent used, concentration should not be greater than 0.1 mL/L and should be same in all vessels | • Virkon S for Aquaculture was tested in triplicate at concentrations of 2 ppm, 4 ppm, 6 ppm, and 8 ppm (p. 13). |
| **Controls**<br>• One dilution water control and, if relevant, one solvent control | • Three control tanks were tested (p. 13). |
| **Replicates Per Dose**<br>• At least 2 replicates per concentration | • Each treatment was conducted in triplicate tanks (p. 13). |
| **Frequency of Analytical Determinations and Measurements:**<br>• During test, concentration of test substance determined at a minimum of 5x is necessary<br>• If study lasts more than 1 month, determinations should be made at least once a week | • The study author did not report any monitoring of the test substance concentration throughout the study period. |
| **Duration of Test**<br>• Should start as soon as possible after eggs fertilized<br>• Should continue until at least all control fish have been free-feeding<br>• Species-dependent requirements:<br>Rainbow trout – 2 weeks after controls are free-feeding (or 60 days post-hatch)<br>Fathead minnow – 32 days from start of test (or 28 days post-hatch)<br>Zebra fish – 30 days post-hatch<br>Ricefish – 30 days post-hatch<br>Sheepshead minnow – 32 days from start of test (or 28 days post-hatch) | • All fish were newly hatched prior to the initiation of the test; however, the exact age of the fish were not provided. |

| Guideline Criteria | Reported Information |
|---|---|
| **Survival Criteria (of controls)**<br>• Hatching success (percent):<br>Rainbow trout – >66<br>Fathead minnow – >66<br>Zebra fish – none provided in guidelines<br>Ricefish – none provided in guidelines<br>Sheepshead minnow – >75<br><br>• Post-Hatch success (percent)<br>Rainbow trout – 70<br>Fathead minnow – 70<br>Zebra fish – 70<br>Ricefish – 80<br>Sheepshead minnow – 80 | • Hatching success : Not applicable<br><br>• Post hatch success: Not reported. |

**D. Observations**

| Guideline Criteria | Reported Information |
|---|---|
| **Stage of embryonic development:**<br>• Embyronic stage at beginning of exposure to the test substance should be verified as precisely as possible | • Not applicable to this study. |
| **Hatching and survival:**<br>• Observations should be made at least once daily and numbers recorded<br>• Dead embryos, larvae, and juvenile fish should be removed as soon as observed | • Mortalities were removed and recorded daily and any moribund fish were removed, dissected, fixed in buffered formalin, and preserved for pathological evaluation (p. 6). |
| **Abnormal appearance:**<br>• Number of larvae or fish showing abnormality of body form should be recorded at adequate intervals depending on duration of test<br>• Should only be removed upon death | • Fish were sampled for histology routinely at 50 days, 100 days. Six fish were sampled and fixed, routinely, for examination of all organs (p. 13). |
| **Abnormal behavior:**<br>• Abnormalities should be recorded at adequate intervals depending on duration of test | • The study author did not include any record of the fish behavior. |

| Guideline Criteria | Reported Information |
|---|---|
| **Weight:**<br>• At end of test, all surviving fish must be weighed (individual weights preferred but if fish are especially small, may be weighed in groups by test vessel; dry weights (25 hr at 60°C) preferable to wet weights (blotted dry)) | • The fish were weighed every 21 days and weighed approximately 130 grams at the final sampling on day 188 (p. 13-14). |
| **Length:**<br>• At end of test, measurement of length recommended: standard, fork or total length (if caudal fin rot or fin erosion occurs, standard lengths should be used) | • The study author did not report whether fish length was measured. |

12. **REPORTED RESULTS**

| Guideline Criteria | Reported Information |
|---|---|
| **Quality assurance and GLP compliance statements included in report?** | • A quality assurance statement was not provided.<br>• This study was not conducted in compliance with U.S. EPA FIFRA (40 CFR part 160) since it was conducted to support non-U.S. product uses (p. 3). |
| **Name of test and investigator, name and location of laboratory, and start/end dates of test reported?** | • The start date of the study was not provided (p. 1). |
| **Source of test material, lot number, composition, known chemical and physical properties, and identity and concentration of any solvent used reported?** | • The test material was supplied by Antec Dupont; however, no additional information regarding the test material (lot number, chemical/physical properties) were provided (p. 5). |
| **Nominal test concentrations, means of measured values, their standard deviation in the test vessels, and the method by which these were attained?** | • Means of measured values, standard deviations and the method by which they were obtained were not provided. |
| **Evidence that concentrations of test solutions have been satisfactorily maintained within ± 20% of mean measured values?** | • Data regarding the concentration throughout the testing period were not provided. |

| Guideline Criteria | Reported Information |
|---|---|
| **Method of preparation of stock solutions and frequency of renewal?** | • The chemical was prepared at an initial dilution of 1:50 and supplied at an appropriate rate, by pump, so as to supply a final concentration of 2 ppm, 4 ppm, 6 ppm and 8 ppm in the incoming water of each set of tanks (p.13). |
| **Information on characteristics of dilution water?** | • The tanks contained spring water. No additional information on the tank water was provided (p. 13). |
| **Detailed information on feeding?** | • Yes. (p. 13). |
| **Description of test system and test design included?** | • Yes (p. 13). |
| **Water quality within test vessels?** | • These data were not provided. |
| **NOEC and LOEC for each response included?** | • The NOEC was 4 ppm, the LOEC was not reported (p. 5). |
| **Concentration-response data and curves included?** | • A figure showing cumulative mortality at each exposure level was reported; however, the data used to create this graph were not provided (p. 14). |
| **Raw data included?** | • No raw data were provided. |
| **Methods and data records reported?** | • This information was not reported in the study. |
| **Statistical methods reported?** | • The statistical methods used were reported but could not be verified because raw data were not provided (p. 6). |

**Dose Response**

Raw data on the survival of the fish at each concentration were not provided. Only data pertaining to the growth rates of the fish at each particular concentration level were presented in the report. These data are summarized in the table below.

**Growth, Feed Intake, and Feed Conversion Ratio (FCR) of Rainbow Trout Exposed to Continuous Doses of Virkon S for Aquaculture**

| Test Concentration (ppm)[1] | Final Weight (g)[2] | Feed Intake (g)[3] | FCR[4] |
|---|---|---|---|
| Control | 123 ±3 | 130 ± 7 | 1.06 ± 0.05 |
| 2 | 126 ± 6 | 141 ± 4 | 1.13 ± 0.04 |
| 4 | 138 ± 7 | 133 ± 11 | 0.97 ± 0.03 |
| 6 | 131 ± 1 | 119 ± 8 | 0.91 ± 0.06 |

[1] Data not available for 8 ppm exposure to Virkon S for Aquaculture due to complete mortality at first feeding.
[2] Initial average fish weight was 0.08 g.
[3] Feed intake expressed on an average intake per fish basis
[4] Feed conversion ration (FCR) = feed fed (as-is basis)/weight gain (wet-weight basis).

**Statistical Results**

**Statistical Method**:

The study author reported that all appropriate data was analyzed for statistical significance using analysis of variance (ANOVA). A significance level of $p<0.05$ was used and tank mean values were considered as the units of observation for the analysis.

**Results Synopsis**:

The study reported that fish at 2 ppm and 4 ppm did not suffer mortality at first feeding and they and the survivors of 6 ppm then grew on normally under continuous exposure for 100 days and, after the respite period, until the end of the study. At first feeding, 8 ppm was a lethal level and 6 ppm appeared to represent and LC50.

At first feeding:
2 ppm - No mortality
4 ppm - NOEC
6 ppm - LC50
8 ppm - Lethal level

## 13. VERIFICATION OF STATISTICAL RESULTS

**Statistical Method/Results Verification Synopsis:**

Raw data were not provided with the study report; therefore, the reviewer was unable to verify the study author's reported results.

## 14. REVIEWER'S COMMENTS:

No additional reviewer comments.

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**Washington, D.C. 20460**

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 22, 2004

T. Jeffrey Jones
Delta Analytical Corporation
The agent for
**Antec International, Ltd.**
7910 Woodmont Avenue, Suite 1000
Bethesda, Maryland 20814

Subject: **VIRKON S**
EPA Registration No. 62432-1
**VIRKON**
EPA Registration No. 62432-2
Applications Date: November 7, 2003
Final Receipt Date: November 10, 2003

Dear Mr. Jones:

The Agency is currently reviewing information submitted in accordance with FIFRA 6(a)(2) report of studies and incidents with potassium peroxymonosulfate (CAS #70693-62-8), which is the active ingredient in the subject products. However, before we can complete our review of volume 5 of 12 entitled "Elchem 1384 (High Strength Bleach: Acute Oral Toxicity in Rats (MRID #461190-05))," the composition of ***"ElChem 1384"*** must be identified.

Should you have any questions or comments concerning this letter, please contact Dr. Jonathan Chen at (703) 305-1287 or me at (703) 308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

cc: Dr. Chen

# TASK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | |
|---|---|---|
| PRODUCT REVIEWER: R Whitaker | | RMB II TEAM 34 |
| Description of Action: | | EPA File Symbol/Reg No.: 71654-6 |
| Decision No. 351465 | Submission No. 771047 | Fee for Service Action Code: |
| FQPA Action Code: 302 | Non-FQPA Action Code: | Fee for Service Fee: $ |

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | 11 | 01 | 2004 |
| EPA PIN DATE | 11 | 02 | 2004 |
| REVIEWER ASSIGNED DATE | 11 | 10 | 2004 |
| DATE DUE TO PM | 11 | 10 | 2004 |
| DATE DUE OUT OF AGENCY | 11 | 10 | 2004 |

| Type of Data: | Product Chemistry ☐ | Acute Toxicology ☐ | Efficacy ☐ | Environmental Fate ☐ | Ecological Effects ☐ | Chronic Toxicology ☐ | Exposure ☐ |
|---|---|---|---|---|---|---|---|

COMMENTS: NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.

DP Barcode No(s):

| B | For Arctic Slope Contract Only | |
|---|---|---|
| Contractor: Arctic Slope | Contract No.: 0332 | ARCTIC SLOPE/MANAGER |
| Draft Task: Signature _____ _____ (Est. hrs) | Final Task: Signature _____ _____ (Total hrs) | |
| C | Reviewer's Comments: | |

Response Code: 17 Response Date: 11/10/04

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**Washington, D.C. 20460**

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 10, 2004

T. Jeffrey Jones
Delta Analytical Corporation
The agent for
**Antec International, Ltd.**
7910 Woodmont Avenue, Suite 1000
Bethesda, Maryland 20814

Subject: **VIRKON S**
EPA Registration No. 71654-6
Application November 1, 2004

Dear Mr. Jones:

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable since you have agreed in writing to:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) and sec. 4 when the Agency requires all registrants of similar products to submit such data.

2. You will submit Product Chemistry data, 830 Series Guidelines for Part A and B on DuPont manufactured source material, conducted in accordance with the Good laboratory Practices (GLP), within six (6) months from the date of this letter.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Should you have any questions or comments concerning this letter, please contact Renae Whitaker at (703) 308-7003 or me at (703) 308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

enclosure:

**Master Label**

# Virkon® S

BROAD SPECTRUM DISINFECTANT[, FUNGICIDE & ALGAECIDE]

[Fragrance Free] [Reduced Dye] [Fragrance & Dye Free]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)

Effective against Viruses
(including CANINE PARVOVIRUS) ● Bacteria ● Fungi

For Use in Emergency Disease Control (OPT.)

For use in Cleaning and Disinfecting Institutional and Service Facilities including stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters), e.g., cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment.(OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

| ACTIVE INGREDIENTS: | |
|---|---|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | 77.09% |
| TOTAL..... | 100.00% |

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO
See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

[For 1% solution, empty one 1.3 oz. sachet into 1 gal. water]

[TABLET FORM]

[POWDER FORM]

ACCEPTED
with COMMENTS
EPA Letter Dated:
NOV 10 2004

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 71664-6

Front Panel Continued

| FIRST AID | |
|---|---|
| **If in Eyes:** | • Hold eye open and rinse slowly and gently with water for 15-20 minutes.<br>• Remove contact lenses, if present after 5 minutes, then continue rinsing eye.<br>• Call a Poison Control Center or doctor for further treatment advice. |
| **If on Skin or Clothing:** | • Take off contaminated clothing.<br>• Rinse skin immediately with plenty of water for 15-20 minutes.<br>• Call a Poison Control Center or doctor for further treatment advice. |
| **If Swallowed:** | • Call Poison Control Center or doctor immediately for treatment advice.<br>• Have Person sip a glass of water if able to swallow.<br>• Do not induce vomiting unless told to do so by the poison control center or doctor<br>• Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| In case of emergency call 1 800 441 7515. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| **Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage. | |

Net contents:

EPA Reg. No. 71654-6 EPA Est. No. 62432-EN-001

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

Virkon® S is a registered trademark of and manufactured by Antec International Ltd.
a DuPont Company

US Patent No. 4822512

[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

**EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:**

**ANIMAL AND ZOONOTIC PATHOGENS**

**BACTERIA**

Actinobacillus pleuropneumonia
Bacillus cereus
Bordetella avium
Bordetella bronchiseptica
Brucella abortus
Campylobacter jejuni
Helicobacter pylori
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Fistulous withers (Poll Evil)
Haemophilus somnus
Klebsiella pneumoniae
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycobacterium bovis
Mycoplasma gallisepticum
Mycoplasma mycoides
Pasteurella multocida
Pseudomonas aeruginosa
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus equi (Strangles)
Streptococcus pyogenes
Streptococcus suis
Taylorella equigenitalis
Treponema hyodysenteriae

**VIRUSES**

Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Adenovirus (Canine Hepatitis)
Canine Coronavirus
Canine Parainfluenza Virus
Canine Parvovirus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (Type A)
Equine Influenza Virus (The Cough)
Feline Calicivirus

Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Panleukopenia Virus
Feline Parvovirus
Feline Rhinotracheitis Virus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
Newcastle Disease Virus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
SV40 Virus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

**FUNGI**

Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

**PLANT PATHOGENS**

Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

## HUMAN HEALTH PATHOGENS

Helicobacter pylori
Escherichia coli
Human Immunodeficiency Virus (HIV)
Type 1 (on hard, non-porous surfaces)
Klebsiella pneumoniae
Pseudomonas aeruginosa
Salmonella cholerasuis
Salmonella typhimurium
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Trichophyton mentagrophytes (use 2% solution)

## PRECAUTIONARY STATEMENTS
## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER.** Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
**Corrosive statement refers to powder only not in use solution.**

## ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. Fo guidance contact your State Water Board or Regional Office of the EPA.

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

### BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution." Virkon® S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

## GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder or tablet formulation is easily diluted for use in manual or machine operations.

***Virkon® S DILUTION CHART***

***Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water.]***

***Powder***

| *Quantity of Water* | *0.5% Solution* | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Quart* | *0.15 ounces* | *0.3 ounces* | *0.7 ounces* |
| *1 Gallon* | *0.65 ounces* | *1.3 ounces* | *2.7 ounces* |
| *10 Gallons* | *6.7 ounces* | *13.4 ounces* | *26.7 ounces* |
| *50 Gallons* | *33.4 ounces* | *66.8 ounces* | *133.5 ounces* |

***Measuring cup provided.***

*Tablet*

| *Quantity of Water* | *0.5% Solution* | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Pint* | | *1 tablet* | *2 tablets* |
| *1 Quart* | *1 tablet* | *2 tablets* | *4 tablets* |
| *1 Gallon* | *4 tablets* | *8 tablets* | *16 tablets* |

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus. Bacteria - Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella avium and Mycoplasma gallisepticum.] (OPT.)

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

[CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot

and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.] (OPT.)

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.] (OPT.)

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES:

Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

## BOVINE PRODUCTION

[CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of Moraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.] (OPT.)

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS

[CONTROLS: Viruses of Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.] (OPT.)

[APPLICATIONS] A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces such as floors, walls, glasshouse structures, ventilation and other equipment, benches, utensils, trays, pots and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Benches and work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1%% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## AQUACULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

The instructions above call for use of a 1% solution for general disinfection, however, Virkon S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon S may be used at the following dilution rates:

| Disease Organism | Dilution rate | Oz./Gal. |
|---|---|---|
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

## USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon S does <u>not</u> come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon S to pool on surfaces that may be within reach of animals. Do not allow Virkon S to come into direct contact with people.

Allow Virkon S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

## INSTITUTIONAL AND SERVICE FACILITIES (HUMAN HEALTH)

CONTROLS: Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces), Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Trichophyton mentagrophytes. (OPT.)

With Virkon® S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon® S solution on textiles or carpets. Virkon® S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

Cleaning and Disinfecting Non-Food Contact Surfaces: Remove gross dirt and use 1.0% Virkon® S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon® S solution.

Sanitizing Toilet Bowls: After flushing, sprinkle 1 oz. Virkon® S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

Cleaning and Disinfecting Manikins Used in CPR Training: Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon® S solution. Let stand for 10 minutes and rinse with potable water.

Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination: Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST *HIV-1 ON HARD NON-POROUS SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

*Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (Hospitals, Nursing Homes, etc.) or other settings in which there is an expected likelihood of soiling of hard non-porous surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable protective latex gloves, gowns, masks, and eye protection.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

## EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

## STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 27, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MS. NANCY B. LOMAX
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE DIVISION
BMP 23/2161, PO Box 80023
WILMINGTON, DE 19880

Dear Ms. Lomax:

Subject: Transfer of Pesticide Registrations and Data From Company Number 62432 to Company Number 71654

Pursuant to your request in your letter and transfer agreement of August 24, 2004, we have approved the transfer of the following registrations and data from ANTEC INTERNATIONAL LTD, company number 62432 to E.I. DUPONT DE NEMOURS AND COMPANY, company number 71654.

The effective date of these changes is the date of this letter.

| Registered Products | Old EPA Reg. No. | New EPA Reg. No. |
|---|---|---|
| VIRKON S | 62432-1 | 71654-6 |
| VIRKON | 62432-2 | 71654-7 |

| Pending Registered Products | Old EPA File Symbol | New EPA File Symbol |
|---|---|---|
| HYPEROX | 62432-G | 71654-I |

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or

package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated August 24, 2004 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date E.I. DUPONT DE NEMOURS AND COMPANY will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Donna G. Parker
Information Management Specialist
Information Services Branch
Information Resources & Services Div. (7504C)

cc: MR. T. JEFFREY JONES
DELTA ANALYTICAL CORPORATION, AGENT FOR
ANTEC INTERNATIONAL LTD
7910 WOODMONT AVENUE, #1000
BETHESDA, MD 20814

DELTA
ANALYTICAL
CORPORATION

1 November 2004

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, D.C. 20460

Subject: Virkon S; EPA Reg. No. 62432-1 (now 71654-6); Your Letter Dated 21 October 2004

Dear Adam:

Following up on our telephone conversation on Thursday, I am responding to your letter of October 21, 2004 (attached). To support my response I am submitting the following information:

- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed Product Label (5 copies); one copy with proposed changes highlighted

Your letter addressed product chemistry, efficacy and labeling issues which are addressed in turn below.

Product Chemistry

With respect to the product chemistry issues, DuPont is prepared to address the following data requirements for DuPont manufactured source material by submitting or citing appropriate data within six months of label approval:

- 830.1750 Certified Limits
- 830.1800 Analytical Method
- 830.7220 Density
- 830.7000 pH
- 830.6314 Oxidation/Reduction
- 830.6315 Flammability
- 830.6317 Storage Stability
- 830.6320 Corrosion Characteristics
- 830.6321 Dielectric Breakdown Voltage

7910 Woodmont Avenue Suite 1000 Bethesda Maryland 20814
(301) 652 5495 FAX (301) 652-5408

Efficacy Comments

The efficacy comments revolve around two common themes: First, the test conditions under which the data were collected vary in a few cases, e.g., hard water and/or a soil load was not used and in one case a 2% solution was necessary to achieve efficacy. Second, in some cases only one lot of test material was used, neutralizer effectiveness testing was not conducted, GLP requirements were not observed, etc. As we've discussed none of these data were collected for EPA submission since it involves animal, rather than public health claims. Now that the Agency has reviewed the data, we question the advisability of using the same standard for judging animal health data as for public health data. If the Agency ultimately decides it must use the same standard, it should give DuPont time to collect and submit the additional data and approve the proposed claims on a time-limited basis in the meantime. Nonetheless, as we agreed, DuPont has withdrawn most of the claims in question in order to expedite approval of other pending and critical changes to the Virkon S registration.

Note that DuPont has not withdrawn claims for those organisms listed in item no. 6 under unacceptable data as these claims were previously approved by the Agency and your label comments appropriately did not request their deletion.

Label Comments

1. The proposed label claims that the product, Virkon S. is a disinfectant on hard, nonporous surfaces in the presence of 400 ppm hard water and 5% organic material when used for a contact time of 10 minutes at a 1:100 dilution against the following microorganisms: *Chlamydia psittaci* Spring Viremia of carp virus are not acceptable.

   Response: These claims have been removed from the proposed label.

2. The proposed label claims that the product, Virkon S, is a disinfectant at higher dilution rates for the following microorganisms: African swine fever virus (at a 1:800 dilution), Chicken anemia virus (at a 1:250 dilution), Avian influenza virus (at a 1:312 dilution), Infectious bursal disease virus (at a 1:250), Transmissible gastroenteritis virus (at a 1:450 dilution), and *Mycoplasma mycoides* (at a 1:200 dilution) are not acceptable.

   Response: These claims have been removed from the proposed label.

3. The proposed label claims that the product, Virkon S, is a disinfectant at higher dilution rates for the following microorganisms are not acceptable:

   Classical swine fever virus (at a 1:150 dilution)
   Foot and mouth disease virus (at a 1:1300)
   Marek's disease virus (at a 1:200 dilution)

Newcastle disease virus (at a 1:280 dilution)
Swine vesicular disease virus (at a 1:200 dilution)

Response: These claims have been removed from the proposed label.

4. The proposed label continues to claim effectiveness against *Candida albicans* [see page 5 and 12 of the proposed label; Human Health Pathogens section and Institutional and Service Facilities section, respectively], although the applicant said that such claims have been removed. You must comply with removal of the claims against *Candida albicans*.

Response: These claims have been removed from the proposed label.

5. You must make the following changes to the proposed label, as appropriate:

(a) On page 8, change "Maraxella bovis" to read Moraxella bovis."
(b) On page 10, change "Foot and Mouse Disease Virus" to read "Foot and Mouth Disease Virus."
(c) On the page 12, change "or other textiles only it area is tested" to read "or other textiles only if area is tested."

Response: The requested changes have been made.

6. On page 5 of the proposed label, under the section Broad Spectrum Disinfectant, there are ambiguous statements that need to be clarified. Briefly the statement, "Virkon S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm AOAC hard water and 5% organic material," is misleading. As mentioned in the Conclusion section, several studies were unclear concerning the final concentration of hard water and the presence/absence of organic material. This statement must be corrected to reflect only the microorganisms that were subjected to the stated test conditions (400 ppm and organic material). Furthermore, some of the test conditions required greater than 1% solution to demonstrate efficacy (i.e., *Trichophyton mentagrophytes),* again making the statement listed above inaccurate and ambiguous.

Response: The proposed label has been modified to qualify claims by inserting "no hard water," "no organic soil load," and "use 2% solution" where appropriate.

7. Special instructions are required when claims against Human Immunodeficiency Virus (HIV) are proposed. An example of these special instructions is listed below:

Special Instructions for Cleaning and Decontamination Against HIV-1 on hard, non-porous surfaces/objects soiled with blood/body fluids.

Personal Protection: Clean-up should always be done wearing protective latex gloves, gowns, masks, and eye-protection.

Cleaning Procedure: Blood and other body fluids containing HIV-1 must be thoroughly cleaned from surfaces and objects before application of [product].

Disposal of Infectious Materials: Blood. body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Response: The proposed label has been modified as requested.

8. The declaration on the label of "25% Dye" is misleading and must be removed. The intended implication is that the formula contains 25% of the dye contained in the basic formulation.

Response: The phrase "reduced dye" has been substituted for "25% dye."

Miscellaneous Label Changes

Consistent with the recent registration transfer from Antec International Ltd. to E.I. DuPont de Nemours and Company (attached), I have changed the company name and address, EPA Reg. No. and emergency contact numbers on the proposed label.

If you have any questions regarding this submission, please contact me at jjones@delta-ac.com. Thanks for your assistance.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd., a DuPont Company

Enclosures

highlighted copy



**Master Label**

# Virkon® S

BROAD SPECTRUM DISINFECTANT[, FUNGICIDE & ALGAECIDE]

[Fragrance Free] [Reduced Dye] [Fragrance & Dye Free]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)

Effective against Viruses
(including CANINE PARVOVIRUS) ● Bacteria ● Fungi

For Use in Emergency Disease Control (OPT.)

For use in Cleaning and Disinfecting Institutional and Service Facilities including stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses. (OPT.)

For Use in Emergency Response and On-site Cleanup (emergency response calls, crime scenes, traffic accidents, fires, flood, natural and other disasters), e.g., cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, paved surfaces; and equipment such as SCBA, coats, boots, hats, masks, gloves, axes, Jaws of Life and similar emergency equipment.(OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

| ACTIVE INGREDIENTS: | |
|---|---|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | 77.09% |
| TOTAL..... | 100.00% |

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO
See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

[For 1% solution, empty one 1.3 oz. sachet into 1 gal. water]

[TABLET FORM]

[POWDER FORM]

Front Panel Continued

| FIRST AID | |
|---|---|
| **If in Eyes:** | • Hold eye open and rinse slowly and gently with water for 15-20 minutes.<br>• Remove contact lenses, if present after 5 minutes, then continue rinsing eye.<br>• Call a Poison Control Center or doctor for further treatment advice. |
| **If on Skin or Clothing:** | • Take off contaminated clothing.<br>• Rinse skin immediately with plenty of water for 15-20 minutes.<br>• Call a Poison Control Center or doctor for further treatment advice. |
| **If Swallowed:** | • Call Poison Control Center or doctor immediately for treatment advice.<br>• Have Person sip a glass of water if able to swallow.<br>• Do not induce vomiting unless told to do so by the poison control center or doctor<br>• Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| In case of emergency call 1 800 441 7515. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| **Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage. | |

Net contents:

EPA Reg. No. 71654-6 EPA Est. No. 62432-EN-001

Manufactured for:
E.I.. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

Virkon® S is a registered trademark of and manufactured by Antec International Ltd.
a DuPont Company

US Patent No. 4822512

[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

**EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:**

**ANIMAL AND ZOONOTIC PATHOGENS**

**BACTERIA**

Actinobacillus pleuropneumonia
Bacillus cereus
Bordetella avium
Bordetella bronchiseptica
Brucella abortus
Campylobacter jejuni
Helicobacter pylori
~~Chlamydia psittaci~~
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Fistulous withers (Poll Evil)
Haemophilus somnus
Klebsiella pneumoniae
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycobacterium bovis
Mycoplasma gallisepticum
Mycoplasma mycoides
Pasteurella multocida
Pseudomonas aeruginosa
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus equi (Strangles)
Streptococcus pyogenes
Streptococcus suis
Taylorella equigenitalis
Treponema hyodysenteriae

**VIRUSES**

Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Adenovirus (Canine Hepatitis)
Canine Coronavirus
Canine Parainfluenza Virus
Canine Parvovirus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (Type A)

Equine Influenza Virus (The Cough)
Feline Calicivirus
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Panleukopenia Virus
Feline Parvovirus
Feline Rhinotracheitis Virus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
Newcastle Disease Virus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
~~*Rhabdovirus carpio* (Spring Viremia of Carp (SVC) virus)~~
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
SV40 Virus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

**FUNGI**

Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

**PLANT PATHOGENS**

Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

## HUMAN HEALTH PATHOGENS

Helicobacter pylori
~~Candida albicans~~
Escherichia coli
Human Immunodeficiency Virus (HIV)
Type 1 (on hard, non-porous surfaces)
Klebsiella pneumoniae
Pseudomonas aeruginosa
Salmonella cholerasuis
Salmonella typhimurium
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Trichophyton mentagrophytes (use 2% solution)

## PRECAUTIONARY STATEMENTS
## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER.** Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

**Corrosive statement refers to powder only not in use solution.**

## ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. Fo guidance contact your State Water Board or Regional Office of the EPA.

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

### BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution." Virkon® S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

## GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder or tablet formulation is easily diluted for use in manual or machine operations.

***Virkon® S DILUTION CHART***

***Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water.]***

***Powder***

| *Quantity of Water* | *0.5% Solution* | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Quart* | *0.15 ounces* | *0.3 ounces* | *0.7 ounces* |
| *1 Gallon* | *0.65 ounces* | *1.3 ounces* | *2.7 ounces* |
| *10 Gallons* | *6.7 ounces* | *13.4 ounces* | *26.7 ounces* |
| *50 Gallons* | *33.4 ounces* | *66.8 ounces* | *133.5 ounces* |

***Measuring cup provided.***

*Tablet*

| *Quantity of Water* | *0.5% Solution* | *1% Solution* | *2% Solution* |
|---|---|---|---|
| *1 Pint* | | *1 tablet* | *2 tablets* |
| *1 Quart* | *1 tablet* | *2 tablets* | *4 tablets* |
| *1 Gallon* | *4 tablets* | *8 tablets* | *16 tablets* |

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus. Bacteria - Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella avium and Mycoplasma gallisepticum.] (OPT.)

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

[CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot

and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.] (OPT.)

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EQUINE PRODUCTION

### BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.] (OPT.)

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES:

Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

## BOVINE PRODUCTION

[CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of Moraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.] (OPT.)

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

## COMPANION ANIMALS

[CONTROLS: Viruses of Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.] (OPT.)

[APPLICATIONS] A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces such as floors, walls, glasshouse structures, ventilation and other equipment, benches, utensils, trays, pots and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Benches and work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1%% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## AQUACULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

## EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

## DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

The instructions above call for use of a 1% solution for general disinfection, however, Virkon S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon S may be used at the following dilution rates:

| Disease Organism | Dilution rate | Oz./Gal. |
|---|---|---|
| ~~African Swine Fever Virus~~ | ~~1:800~~ | ~~0.2~~ |
| ~~Chicken Anemia Virus~~ | ~~1:250~~ | ~~0.6~~ |
| ~~Classical Swine Fever Virus (Hog Cholera Virus)~~ | ~~1:150~~ | ~~0.9~~ |
| ~~Foot and Mouth Disease Virus~~ | ~~1:1300~~ | ~~0.1~~ |
| ~~Highly Pathogenic Avian Influenza Virus~~ | ~~1:312~~ | ~~0.5~~ |
| ~~Marek's Disease Virus~~ | ~~1:200~~ | ~~0.7~~ |
| ~~Newcastle Disease Virus~~ | ~~1:280~~ | ~~0.5~~ |
| ~~Infectious Bursal Disease Virus~~ | ~~1:250~~ | ~~0.6~~ |
| ~~Swine Vesicular Disease Virus~~ | ~~1:200~~ | ~~0.7~~ |
| ~~Transmissible Gastroenteritis Virus~~ | ~~1:450~~ | ~~0.3~~ |
| ~~Mycoplasma mycoides (Contagious Bovine Pleuropneumonia)~~ | ~~1:200~~ | ~~0.7~~ |
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

## USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon S to pool on surfaces that may be within reach of animals. Do not allow Virkon S to come into direct contact with people. Allow Virkon S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

## INSTITUTIONAL AND SERVICE FACILITIES (HUMAN HEALTH)

CONTROLS: Human Immuno-Deficiency Virus (HIV) Type 1 (on hard, non-porous surfaces), Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, ~~Candida albicans~~ and Trichophyton mentagrophytes. (OPT.)

With Virkon® S, only one product is needed to clean and disinfect all surfaces except acid-sensitive surfaces such as copper, brass, or aluminum. Do not use Virkon S on these acid-sensitive surfaces. Avoid splashing Virkon® S solution on textiles or carpets. Virkon® S may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.

Cleaning and Disinfecting Non-Food Contact Surfaces: Remove gross dirt and use 1.0% Virkon® S solution prepared according to the Dilution Chart below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon® S solution.

Sanitizing Toilet Bowls: After flushing, sprinkle 1 oz. Virkon® S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

Cleaning and Disinfecting Manikins Used in CPR Training: Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon® S solution. Let stand for 10 minutes and rinse with potable water.

Cleaning and Disinfecting Hard, Non-porous Surfaces Suspected of HIV Type 1 Contamination: Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then

scoop into plastic bag. Treat bag and its contents as infectious medical waste. Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST *HIV-1 ON HARD NON-POROUS SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

*Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (Hospitals, Nursing Homes, etc.) or other settings in which there is an expected likelihood of soiling of hard non-porous surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable protective latex gloves, gowns, masks, and eye protection.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

EMERGENCY RESPONSE AND ON-SITE CLEANUP

Cover heavy spillage of body fluids with Virkon® S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon® S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals

*Please read instructions on reverse before completing form.* Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number: 295783

## Application for Pesticide - Section I

1. Company/Product Number: 71654-6
2. EPA Product Manager: Adam Heyward
3. Proposed Classification: ☑ None ☐ Restricted
4. Company/Product (Name): Virkon S
PM#: 34
5. Name and Address of Applicant *(Include ZIP Code)*: E.I. DuPont de Nemours and Company c/o Delta Analytical Corporation, 7910 Woodmont Ave. Suite 1000, Bethesda, MD 20814
☐ *Check if this is a new address*
6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

## Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated 21 OCT 04
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)
Submission of revised label in response to comments in Agency letter dated 21 October 2004

## Section - III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) |
| [redacted]*rtification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) Retail Container
5. Location of Label Directions: ☐
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

## Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Jeff Jones | Agent, Antec Int'l Ltd. a DuPont Co. | 302 652 5495 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Jeff Jones
3. Title: Agent, Antec Int'l Ltd. a DuPont Co.
4. Typed Name: Jeff Jones
5. Date: November 1, 2004



EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

*Please read instructions on reverse before completing form.* Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
295783

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification ☐ None ☐ Restricted |
|---|---|---|
| 4. Company/Product (Name) | PM# | |
| 5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address* | 6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |

## Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

## Section - III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes* ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____ |
| *certification must be submitted | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☐ Label ☐ Container | | ☐ On Label ☐ On Labeling accompanying product |

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

## Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

| 2. Signature | 3. Title |
|---|---|
| 4. Typed Name | 5. Date |



EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too" reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 27, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MS. NANCY B. LOMAX
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE DIVISION
BMP 23/2161, PO Box 80023
WILMINGTON, DE 19880

Dear Ms. Lomax:

Subject: Transfer of Pesticide Registrations and Data From Company Number 62432 to Company Number 71654

Pursuant to your request in your letter and transfer agreement of August 24, 2004, we have approved the transfer of the following registrations and data from ANTEC INTERNATIONAL LTD, company number 62432 to E.I. DUPONT DE NEMOURS AND COMPANY, company number 71654.

The effective date of these changes is the date of this letter.

| Registered Products | Old EPA Reg. No. | New EPA Reg. No. |
|---|---|---|
| VIRKON S | 62432-1 | 71654-6 |
| VIRKON | 62432-2 | 71654-7 |

| Pending Registered Products | Old EPA File Symbol | New EPA File Symbol |
|---|---|---|
| HYPEROX | 62432-G | 71654-I |

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or

package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated August 24, 2004 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date E.I. DUPONT DE NEMOURS AND COMPANY will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Donna G. Parker
Information Management Specialist
Information Services Branch
Information Resources & Services Div. (7504C)

cc: MR. T. JEFFREY JONES
DELTA ANALYTICAL CORPORATION, AGENT FOR
ANTEC INTERNATIONAL LTD
7910 WOODMONT AVENUE, #1000
BETHESDA, MD 20814

# TASK ASSIGNMENT FORM
## Antimicrobial Division/Regulatory Management Branch II

| A | Completed by Product Manager | | |
|---|---|---|---|
| PRODUCT REVIEWER: Renee Whitaker | | | RMB II TEAM 34 |
| Description of Action: | | | EPA File Symbol/Reg No.: 62432-1 |
| Decision No. | Submission No. 763013 | | Fee for Service Action Code: |
| FQPA Action Code: | Non-FQPA Action Code: | | Fee for Service Fee: $ |
| | MONTH | DAY | YEAR |
| APPLICATION DATE | 01 | 05 | 2004 |
| EPA PIN DATE | 06 | 09 | 2004 |
| REVIEWER ASSIGNED DATE | 06 | 29 | 2004 |
| DATE DUE TO PM | | | 2004 |
| DATE DUE OUT OF AGENCY | | | 2004 |

| Type of Data: | Product Chemistry ☐ | Acute Toxicology ☐ | Efficacy ☒ | Environmental Fate ☐ | Ecological Effects ☐ | Chronic Toxicology ☐ | Exposure ☐ |
|---|---|---|---|---|---|---|---|

COMMENTS: NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.

DP Barcode No(s):

| B | For Arctic Slope Contract Only | | |
|---|---|---|---|
| Contractor: Arctic Slope | | Contract No.: 0332 | ARCTIC SLOPE/MANAGER |
| Draft Task: Signature _____ _____ (Est. hrs) | | Final Task: Signature _____ _____ (Total hrs) | |
| C | Reviewer's Comments: | | |

| Response Code: 11 | Response Date: 10/21/04 |
|---|---|

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**Washington, D.C. 20460**

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

**October 21, 2004**

T. Jeffrey Jones, Agent
Delta Analytical Corporation
Antec International Ltd.
7910 Woodmont Avenue, Suite 1000
Bethesda, MD 20814

Subject: **Virkon S Disinfectant**
EPA Registration No. 62432-1
Letter Dated January 5, 2004

Dear Mr. Jones:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is unacceptable for the following reasons.

**Proposed Amendments**:

- Additional efficacy claims (review of efficacy data)
- Revised basic and several alternate confidential statement of formula (CSF) (see CSFs dated 01/05/04)

**Product Chemistry Comments**:

1. You claimed exemption from the requirements to submit data responding to series 830, Group B because the subject product is an end-use product. The active ingredients, however, are not purchased from a registered source, therefore, requiring the formulator to satisfy the data requirements of Group B. The source material postassium monoperoxysulfate in the referenced MRID #410574-01 was [redacted]. The source of the same active ingredient in the current application is Dupont Chemicals Inc., an unregistered supplier.

2. MRID #410574-01: The data contained in the study responds to the requirements of OPPTS Test Guidelines 830, Group B. The report is unacceptable. You must submit data responding to all applicable test guidelines of Groups A & B.

3. MRID #420924-01: The data contained in the study responds to the requirements of 830.6317. The study is unacceptable due to it not being of the source material of the current unregistered supplier.

4. Alternative language describing the decreased dye content is required for the alternative formulation having [redacted] dye.

**Efficacy Comments**:

**A. Acceptable data (Bacteria and Fungi):**

1. The submitted confirmatory efficacy data support the use of the tablet form of the product, Virkon S, as a broad-spectrum disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (fetal bovine serum) for contact time of 10 minutes at a 1:100 use dilution: *Salmonella choleraesuis* and *Staphylococcus aureus*.

2. The submitted efficacy data support the use of the product, Virkon S, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (fetal bovine serum) for a contact time of 10 minutes at a 1:100 dilution:

*Bacillus cereus*
*Salmonella typhimurium*
*Staphylococcus epidermidis*
*Streptococcus pyogenes*
*Shigella sonnei*
*Listeria monocytogenes*
*Pseudomonas aeruginosa*
*Brucella abortus*
*Campylobacter jejuni*
*Escherichia coli*
*Klebsiella pneumoniae*

3. The submitted efficacy data (MRID No. 461660-11) support the use of the product, Virkon S, as a disinfectant with fungicidal activity against ***Trichophyton mentagrophytes*** on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (fetal bovine serum) for a contact time of 10 minutes at a use dilution of 1:50. No growth was observed in any subcultures of the carriers tested against the two product lots. Neutralization confirmation testing showed positive growth of the organism. Viability controls were positive for growth. Dried carrier counts were at least $10^4$, which is consistent with the Agency's interim policy. [ For more details about this interim policy, see Section III of this efficacy report.]

**Unacceptable data:**

1. The submitted efficacy data (MRID No. 462650-03) do not support the use of the product, Virkon S, as a disinfectant against ***Mycoplasma mycoides* subspecies *mycoides*** on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) for a contact time of 10 minutes at a 1:100 dilution and 1:200 dilution. Dried carriers counts were at least $10^4$. Although no growth was observed in the subcultures, only one product lot was tested thus not satisfying the requirements set forth by DIS/TSS-1. Furthermore, GLP was not followed. Finally, label claims for efficacy at 400 ppm synthetic hard water was not substantiated by the submitted data.

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2. The submitted efficacy data (MRID No. 461660-06) do not support the use of the product, Virkon S, as a disinfectant against ***Chlamydia psittaci*** on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (serum) for a contact time of 10 minutes at a 1:100 dilution. Neutralizer effectiveness testing was not conducted, to determine if residual active ingredients are present after neutralization. Neutralization effectiveness is determined by the following procedure: One lot of the test agents are used for the neutralizer effectiveness control. This control will be processed exactly as the test procedure but instead of the inoculum, balanced salt solution is added. Post test, and neutralization, a 1.0 mL sample is divided into two portions, one for cytotoxicity and the other for neutralizer effectiveness. The neutralized sample is serially diluted in balanced salt solution and the test organisms will be added to each dilution and incubated for a period equivalent to the contact time. These samples are then used to inoculate host cells.

**B. Acceptable data (Viruses):**

1. The submitted efficacy data (MRID No. 461660-19) support the use of the product, Virkon S, as a disinfectant with virucidal activity against **Porcine circovirus type II** on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (serum) for a contact time of 10 minutes at a 1:200 dilution. Complete inactivation (no growth) was indicated in all dilutions tested. Cytotoxicity was not observed. A recoverable titer of at least $10^4$ was observed.

**Unacceptable data (higher rates):**

1. For approval of higher dilution rates (MRID No. 461660-12) against **Classical swine fever virus**, **Foot and Mouth Disease virus**, **Marek's Disease virus**, **fowl pest**, general orders and **Newcastle virus** are not acceptable due to the lack of efficacy data. The data package submitted was a proposal of potential studies, with no efficacy data. Until the proper efficacy data is submitted to satisfy the higher dilution rates, the use of the product, Virkon S, as a disinfectant against the listed microorganisms is not supported.

2. The submitted efficacy data (MRID No. 461660-13) do not support the use of the product, Virkon S, as a disinfectant against **Infectious bursal disease (Gumboro) virus** on hard, non-porous surfaces at a dilution of 1:250, due to the following deficiencies:

(a) No contact time was included in the study;
(b) Only one product lot was tested, not the required two;
(c) The soil load was not specified;
(d) The target concentration of hard water was not provided;
(e) Test results for each replication were not provided per DIS/TSS-3; only a narrative summary of the test results was provided;
(f) It is unclear whether four determinations per each dilution were assayed;
(g) Neutralizer effectiveness testing does not appear to have been conducted;
(h) GLP was not followed; the study was conducted in 1986.

3. The submitted efficacy data (MRID No. 4616660-14) do not support the use of the product, Virkon S, as a disinfectant against **Chicken anemia virus** on hard, non-porous surfaces at use dilutions of 1:125 and 1:250, due to the following deficiencies:

(a) A 30 minute contact time, with agitation every 10 minutes was used in the test protocol, however the label specified a 10 minute contact time;
(b) Only one product lot was tested, not the required two;
(c) The purpose of Baker's yeast was not specified;
(d) The target concentration of the hard water used during testing was not provided;
(e) Test results for each replication were not provided per DIS/TSS-3
(f) It is unclear whether four determinations per each dilution were assayed;
(g) Neutralizer effectiveness testing does not appear to have been conducted;
(h) GLP was not followed; study was conducted in 1990.

4. The submitted efficacy data (MRID No. 461660-18) do not support the use of the product, Virkon S, as a disinfectant against **Avian influenza virus** on hard, non-porous surfaces at use dilutions of 1:280, 1:300, and 1:320, due to the following deficiencies:

(a) Only one product lot was tested, not the required two
(b) The soil load was not specified;
(c) The target concentration of the hard water used during testing was not provided;
(d) It does not appear that four determinations per each dilution were assayed;
(e) Neutralizer effectiveness testing does not appear to have been conducted;
(f) GLP was not followed; the study was conducted in 1985
(g) Data submitted for Avian influenza virus is to be used as a substitute for Newcastle disease virus. The Agency has not determined if Avian influenza virus is a surrogate for Newcastle disease virus. Avian influenza virus is classified in the family of viruses labeled Orthomyxoviridea, while Newcastle disease is classified in the family of viruses labeled Paramyxoviridea. Although both families of viruses are single-stranded RNA viruses, there exist some substantial differences that cannot be overlooked.

5. The submitted efficacy data (MRID No. 462650-01) do not support the use of the product, Virkon S, as a disinfectant against **Spring Viremia of Carp virus** on hard, non-porous surfaces at use dilutions of 1:100, 1:500, 1:1000, and 1:2500, due do the following deficiencies,

(a) Only one product lot was tested, not the required two;
(b) The test protocol did not include a neutralization step;
(c) GLP was not followed; the study was conducted in 2003;
(d) A 30-minute contact time was used during testing, not the labeled-specified 10 minutes;

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(e) The recommended use-dilution is unclear from the present data. CPE observed at the 1:100 dilution, is not represented of efficacy. In the Conclusion section of the data report, it is stated that "additional work should be done to further replicate these results. More importantly, additional trials should be conducted at a Virkon-S concentration of 1:250 ..."

6. The submitted efficacy data (MRID No. 462650-02) do not support the use of the product, Virkon S, as a disinfectant against **Calf rotavirus**, **Duck adenovirus**, **Infectious bovine rhinotracheitis virus**, **Parvovirus**, **Parainfluenza virus**, **Bovine diarrheal diarrhea virus**, **Equine arteritis**, **Pseudorabies**, **Turkey Herpes virus** and **Transmissible gastroenteritis virus** on hard, non-porous surfaces at use dilutions of 1:100, due to the following deficiencies,

(a) Neutralizer effectiveness testing (where a low level of virus is added);
(b) Cytotoxicity was not conducted or reported;
(c) GLP was not followed; study was conducted in 1991;
(d) Testing was not conducted using 400 ppm synthetic water, therefore the label must to modified to reflect change;
(e) The Conclusions section of the laboratory report refers to a different product (i.e., Powder Detergent/Disinfectant) and different product lot numbers (i.e., Lot Nos. 1468-56 and 1468-57). The appropriate conclusions should be submitted to correct the efficacy study;
(f) According to DIS/TSS-7, disinfectants must be tested against a recoverable titer of at least $10^4$ from the test surfaces. Viral titers for Calf rotavirus, Transmissible gastroenteritis virus, Parvovirus, Duck adenovirus (Egg Drop syndrome), Infectious bovine rhinotracheitis virus (ranged from $3.2 \times 10^3$ to $4.7 \times 10^3$ $CCID_{50}$/mL).

7. The submitted efficacy data (MRID No. 462650-04) do not support the use of the product, Virkon S, as a disinfectant against **African swine fever virus** on hard, non-porous surfaces at use dilutions of 1:500, 1:600, 1:700, and 1:800, due to the following deficiencies,

(a) Only one product lot was tested, not the required two;
(b) The product was tested in the presence of a 1% organic soil load, not a 5% organic soil load;
(c) The product was tested in the presence of 342 ppm hard water, not 400 ppm hard water;
(d) Test results for each replication were not provided, per DIS/TSS-3.
(e) Three determinations per each dilution were assayed, not the required four.
(f) The test protocol did not include a neutralization step;
(g) GLP was not followed; the study was conducted in 2002;
(h) A 30-minute contact time was used during testing, not the label-specified 10 minutes.

**C. Label Comments:**

1. The proposed label claims that the product, Virkon S, is a disinfectant on hard, non-porous surfaces in the presence of 400 ppm hard water and 5% organic material when used for a contact time of 10 minutes at a 1:100 dilution against the following microorganisms: *Chlamydia psittaci* Spring Viremia of carp virus are not acceptable.

2. The proposed label claims that the product, Virkon S, is a disinfectant at higher dilution rates for the following microorganisms: African swine fever virus (at a 1:800 dilution), Chicken anemia virus (at a 1:250 dilution), Avian influenza virus (at a 1:312 dilution), Infectious bursal disease virus (at a 1:250), Transmissible gastroenteritis virus (at a 1:450 dilution), and *Mycoplasma mycoides* (at a 1:200 dilution) are not acceptable.

3. The proposed label claims that the product, Virkon S, is a disinfectant at higher dilution rates for the following microorganisms are not acceptable:

   Classical swine fever virus (at a 1:150 dilution)
   Foot and mouth disease virus (at a 1:1300)
   Marek's disease virus (at a 1:200 dilution)
   Newcastle disease virus (at a 1:280 dilution)
   Swine vesicular disease virus (at a 1:200 dilution)

4. The proposed label continues to claim effectiveness against *Candida albicans* [see page 5 and 12 of the proposed label; Human Health Pathogens section and Institutional and Service Facilities section, respectively], although the applicant said that such claims have been removed. You must comply with removal of the claims against *Candida albicans*.

5. You must make the following changes to the proposed label, as appropriate:

   (a) On page 8, change "Maraxella bovis" to read Moraxella bovis."
   (b) On page 10, change "Foot and Mouse Disease Virus" to read "Foot and Mouth Disease Virus."
   (c) On the page 12, change "or other textiles only it area is tested" to read "or other textiles only if area is tested."

6. On page 5 of the proposed label, under the section Broad Spectrum Disinfectant, there are ambiguous statements that need to be clarified. Briefly the statement , "Virkon S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. . . . Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm AOAC hard water and 5% organic material," is misleading. As mentioned in the Conclusion section, several studies were unclear concerning the final concentration of hard water and the presence/absence of organic material. This statement must be corrected to reflect only the microorganisms that were subjected to the stated test conditions (400 ppm and organic material). Furthermore, some of the test conditions required greater

than 1% solution to demonstrate efficacy (i.e, *Trichophyton mentagrophytes*), again making the statement listed above inaccurate and ambiguous.

7. Special instructions are required when claims against Human Immunodeficiency Virus (HIV) are proposed. An example of these special instructions is listed below:

**Special Instructions for Cleaning and Decontamination Against HIV-1 on hard, non-porous surfaces/objects soiled with blood/body fluids."**

**Personal Protection**: Clean-up should always be done wearing protective latex gloves, gowns, masks, and eye-protection.

**Cleaning Procedure**: Blood and other body fluids containing HIV-1 must be thoroughly cleaned from surfaces and objects before application of [product].

**Disposal of Infectious Materials**: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

8. The declaration on the label of "25% Dye" is misleading and must be removed. The intended implication is that the formula contains 25% of the dye contained in the basic formulation.

Note that claims that are inconsistent with efficacy contact time established by testing are unacceptable. For example, a claim of 30 second efficacy is not acceptable if testing and/or use direction requires 2 minute contact time for microorganisms efficacy. The label must list only the contact time established by the efficacy testing DIS/TSS. Often when a product is used, a consumer is unaware of the microbial contamination and possible interactions between multiple contaminants. For it is rare that a surface is consistently contaminated with one species.

**Other Comments**:

For detailed information and consideration, refer to the enclosed EPA/AD Product Science Branch efficacy data evaluation record (DER) dated September 20, 2004 and product chemistry review dated October 19, 2004. If you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

enclosures:

| CONCURRENCES | | | | | | | | |
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
**Antimicrobials Division**

**October 19, 2004**

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Virkon S**

**DP Barcode: D304905** **Reg. No. Or File Symbol: 62432-1**
**Manufacturing-use [ ]** OR **End-use Product [X]**

**TO:** Adam Heyward PM 34 / Renae Whitaker, Team Reviewer
Regulatory Management Branch II
Antimicrobials Division (7510C)

**FROM:** Robert A. Turpin, Chemist R. T.
Product Science Branch, CT Team
Antimicrobials Division (7510C)

**THRU:** Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

10/21/04

**THRU:** Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

**Product Formulation**

| **Active Ingredient(s)** | **% by wt.** |
|---|---|
| Potassium peroxymonosulfate ..... | 21.41 |
| Sodium chloride ..... | 1.50 |

**BACKGROUND:** The registrant has submitted an amendment in response to Agency letters dated July 22 and August 5, 2004, proposing a new basic and several alternate formulations, adding an organism claim, and increasing the dilution rates for specific organisms. In support of the amendment the registrant has submitted Confidential Statements of Formula (CSF) for the basic and several alternate formulations, a proposed product label, a Certification with Respect to Citation of Data and a Data Matrix.

**FINDINGS:**

1. The CSF of the basic formulation is acceptable.

2. The CSF of the alternative formulation "25% dye formulation" is acceptable.

3. The CSFs of the alternative formulations "Tablet formulation", "Fragrance & dye free", and "Fragrance free" are acceptable.

4. The draft product label is not acceptable. The declaration on the label of "25% Dye" is misleading and should be removed. The intended implication is that the formula contains 25% of the dye contained in the basic formulation.

5. MRID #461660-02: The report contains data responding to the requirements of OPPTS Test [redacted]uidelines 830.1550, -1600, -1650, and -1670. The data is acceptable.

6. The applicant claims exemption from the requirements to submit data responding to Series 830, Group B because the subject product is an end-use product. The active ingredients, however, are not purchased from a registered source, therefore, requiring the formulator to satisfy the data requirements of Group B. The source of the material potassium monoperoxysulfate in the reference MRID #410574-01 was [redacted] The source of the same active ingredient in the current application is Dupont Chemicals Inc., an unregistered supplier.

7. MRID #410574-01: The data contained in the study responds to the requirements of OPPTS Test Guidelines 830, Group B. The report is unacceptable.

8. MRID #420924-01: The data contained in the study responds to the requirements of 830.6317. The study is unacceptable due to it not being of the source material of the current unregistered supplier.

**RECOMMENDATIONS:**

1. Alternative language describing the decreased dye content is required for the alternative formulation having [redacted] dye.

2. The applicant must submit data responding to all applicable test guidelines of Groups A & B.

## PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
  - Are all TGAIs used registered? Yes [ ] No [X]
- Integrated formulation system [ ]
- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [ ] No [ ] NA [X]

4c. Physical state of product: Solid, tablet

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Part B
Yes [ ] No [X]

4h. NCs and CLs are acceptable: Yes [X] No [ ] Not acceptable [ ]

| 4i. Active ingredient (s) | NC | LCL | UCL |
|---|---|---|---|
| Potassium peroxymonosulfate | 21.41% | 20.77% | 22.05% |
| Sodium chloride | 1.50% | 1.43% | 1.58% |

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- All impurities of $\geq 0.1\%$ in the product have been identified?
  Yes [ ] No [ ] Not applicable [X]

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC] is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [X] No [ ]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- Sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [ ] No [ ] Not applicable [X]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [X] No [ ] Not on label

5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes [ ] No [ ] *

* The study submitted by reference is not acceptable. New study under GLP must be performed.

1. **PRODUCT CHEMISTRY (830 Series, Part A)**

| Guideline | Acceptance of Information | MRID No. |
|---|---|---|
| 830.1550[1] Product Identity | A | 461660-02 |
| 830.1600 Description of Materials | A | 461660-02 |
| 830.1620 Production Method[2] | NA | |
| 830.1650 Formulation process[3] | A | 461660-02 |
| 830.1670 Formation of impurities[4] | A | 461660-02 |
| 830.1700 Preliminary Analysis[5] | NA | |
| 830.1750 Certified Limits[6] | G | |
| 830.1800 Analytical Method[7] | G | |

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information

[2]For MP/EP products produced by an integrated formulation system.

[3]For products from a TGAI or MP.

[4]May be waived unless actual/possible impurities are of toxicological concern.

[5]Five batch analysis required for products produced by an integrated formulation system.

[6]If different from standard Cls recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

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| 6b. Physical/Chemical Properties* | Acceptance of data | Value or qualitative description | MRID No. |
|---|---|---|---|
| 830.6302 Color | W | | |
| 830.6303 Physical state | A | Solid, tablet | 461660-02 |
| 830.6303 Odor | W | | |
| 830.7200 Melting point | NA | | |
| 830.7220 Density/Relative density/bulk density | G | | |
| 830.7000 pH[1] | G | | |
| 830.6314 Oxidation/Reduction | G | | |
| 830.6315 Flammability | G | | |
| 830.6317 Storage stability | G | | |
| 830.7100 Viscosity | NA | | |
| 830.6319 Miscibility[2] | NA | | |
| 830.6320 Corrosion Character. | G | | |
| 830.6321 Dielectric breakdown | G | | |

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25 $^{0}$C.

[1] If product is dispersible with water

[2] If product is an emulsifiable liquid

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 20, 2004

**MEMORANDUM**

**Subject:** Efficacy Review for EPA Reg. No. 62432-1, Virkon S Disinfectant
DP Barcode: 304907

**From:** Tajah L. Blackburn, Ph.D., Microbiologist 10/6/04
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

**Thru:** Nancy Whyte, Acting Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)
October 8, 2004

**To:** Adam Heyward PM 34/ Renae Whitaker
Regulatory Management II
Antimicrobials Division (7510C)

**Applicant:** Antec International Ltd. c/o Delta Analytical Corporation
Windham Road, Chilton Industrial Estates
Sudbury Suffolk C010 2XD, England

**Formulation from Label**

| Active Ingredient(s) | % by wt. |
|---|---|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride ..... | 1.50% |
| Other Ingredient(s) ..... | 77.09% |
| Total | 100.00% |

## I BACKGROUND

The product, Virkon S (EPA Reg. No. 62432-1), is a registered disinfectant (bactericide, fungicide, virucide) for use on hard, non-porous surfaces in institutional, industrial, and animal care environments. The label claims that the product is an effective disinfectant in the presence of 400 ppm hard water and a 5% organic soil load. The applicant requested to amend the registration of this product to add claims for effectiveness against additional microorganisms, specifically, *Brucella abortus*, *Campylobacter jejuni*, *Chlamydia psittaci*, *Listeria monocytogenes*, *Shigella sonnei*, *Trichophyton mentagrophytes*, Spring Viremia of Carp virus, Swine vesicular disease virus, Mouse parvovirus, and *Xanthomonas axonopodis*.

In addition, the applicant requested to amend the registration to include higher dilution rates for certain microorganisms, namely, African swine fever virus (at a 1:800 dilution), Chicken anemia virus ( at a 1:250 dilution), Classical swine fever virus (at a 1:150 dilution), Foot and mouth disease virus (at a 1:1300 dilution), Avian influenza virus (at a 1:312) dilution, Marek's disease virus (at a 1:200 dilution), Newcastle disease virus (at a 1:280 dilution), Infectious bursal disease virus (at a 1:250 dilution), Swine vesicular disease virus (at a 1:200 dilution), Transmissible gastroenteritis virus (at a 1:450 dilution), *Mycoplasma mycoides* (at a 1:200 dilution), and Porcine circovirus type II (at a 1:200 dilution).

In addition, the applicant has provided results from new studies that support claims for effectiveness (in the presence of a 5% organic soil load) against *Escherichia coli*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, and *Salmonella typhimurium*. Finally, the applicant requested the addition of a tablet formulation of the product (previously distributed as a powder formulation).

Studies were conducted at ATS Labs, located at 2540 Executive Drive in St. Paul, MN 55120; The Institute for Animal Health, Pirbright Laboratory, located on Ash Road in Pirbright Surrey GU26 0NF, UK; MicroBioTest Inc., located at 105B Carpenter Drive in Sterling, VA 20164; MicroBioTest, Inc., located at 14280 Sullyfield Circle #200 in Chantilly, VA 22021; Ministry of Agriculture, Fisheries and Food, Central Veterinary Laboratory, located at New Haw Weybridge, Surrey KT15 3NB, UK; University of Arkansas at Pine Bluff (address not provided); Veterinary Laboratories Agency (Weybridge), located on Woodham Lane in New Haw, Addlestone, Surrey KT15 3NB, UK; and ViroMed Laboratories, Inc., located at 6101 Blue Circle Drive in Minneapolis, MN 55343.

This data package contained EPA Form 8570-1 (Application for Pesticide), a letter from the applicant's representative to the Agency (dated January 5, 2004), eighteen studies (MRID Nos. 461660-01 through 461660-14, 461660-18, 461660-19, and 462650-01 through 462650-04; excluding 461660-02 and 461660-02), Statements of No Data Confidentiality Claims for all eighteen studies, and the proposed label.

## II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces such as vehicles,

floors, walls, ceilings, equipment, instruments, utensils, cages, and containers. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Prepare a use solution by adding 1.3 ounces of the product to 1 gallon of water (a 1:100 dilution). Apply use solution using a mop, sponge, brush, fogger, sprayer or treat by immersion. Allow surfaces to remain wet for 10 minutes. Rinse with water and allow to dry. A pre-cleaning is recommended for heavily soiled surfaces, but a 1:50 solution (2.6 oz. per gallon of water) can be used as an alternative.

The proposed label also included directions for a new use-pattern entitled "Disinfection Limited to Specific and Known Disease Organisms." For this use-pattern, the product, Virkon S, may be used to treat against specific microorganisms at dilution rates less than 1:100. The directions for this new use-pattern list specific dilution rates for 12 microorganisms.

Note– A dilution chart is included on the proposed label. To generate the final concentrations, it appears that several of the added amounts exceed the stated final solution amount (0.5%, 1%, and 2%). Often the final concentrations are "over formulated" to account for potential consumer error. However, there is no consistency in the amount of over-formulation.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria); Confirmatory Efficacy Data Requirements

Under certain circumstances, an applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and to submit only minimal confirmatory efficacy data on his own product to demonstrate his ability to produce an effective formation. Confirmatory data must be developed on the applicant's own finished product. For general broad-spectrum disinfectants, 10 carriers on each of 2 samples representing 2 different product lots must be tested against *Salmonella choleraesuis* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538) using either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Killing on all carriers is required. These Agency standards are presented in DIS/TSS-5.

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria; Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific bacterium with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific bacteria on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least $10^4$ microorganisms survived the carrier-drying step. These Agency standards are presented in DIS/TSS-1.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least $10^4$ from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified AOAC Use-Dilution Method)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least $10^6$ conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required. These Agency standards are presented in DIS/TSS-6.

Note: As an interim policy, the Agency is accepting studies with dried carrier counts that are at least $10^4$ for *Trichophyton mentagrophytes* and *Aspergillus niger*. The Agency recognizes that laboratories are experiencing problems in maintaining dried carrier counts at the $10^6$ level. This interim policy will be in effect until the Agency determines that the laboratories are able to achieve consistent carrier counts at the $10^5$ level.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are also presented in DIS/TSS-2.

## IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

**1. MRID 461660-01 "AOAC Use-Dilution Method" for Antec Virkon S, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – November 19, 2003.**

This study was conducted against *Escherichia coli* (ATCC 11229), *Klebsiella pneumoniae* (ATCC 4352), *Staphylococcus epidermidis* (ATCC 12228), *Salmonella typhimurium* (ATCC 23564), and *Streptococcus pyogenes* (ATCC 19615). Two lots (Lot Nos. 9042 and 10064) of the product, Virkon S, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A use solution was prepared by adding 10 g of the product to 1000 mL of 400 ppm AOAC synthetic hard water (titrated at 398 ppm; a 1:100 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to 10 mL of the use solution for 10 minutes at 20±1°C. Individual carriers were transferred to 10 mL of Universal Neutralizer to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, viability, sterility, neutralization confirmation, and carrier population.

**2. MRID 461660-03 "AOAC Use-Dilution Method" for Virkon S Tablets, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – October 15, 2003.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Salmonella choleraesuis* (ATCC 10708). Two lots (Lot Nos. 2094 and 2143) of the product, Virkon S Tablets, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A use solution was prepared by adding 1 tablet of the product to 500 mL of 400 ppm AOAC synthetic hard water (titrated at 396.5 ppm; a 1:100 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to 10 mL of the use solution for 10 minutes at 20±1°C. Individual carriers were transferred to 10 mL of Universal Neutralizer to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

**3. MRID 461660-04 "The Evaluation of the Efficacy of Virkon S Against *Campylobacter jejuni* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load," by Mary K. Bennett. Study conducted at ViroMed Laboratories, Inc. Study completion date – July 25, 1996.**

This study was conducted against *Campylobacter jejuni* (ATCC 29428). Two lots (Lot Nos. 2032 and 7347) of the product, Virkon S, were tested using the AOAC Use-Dilution Method (modified) as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A 1:100 use solution was prepared using 400 ppm AOAC synthetic hard water (titrated at 405

ppm). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in a 48±4 hour old suspension of the test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to 10 mL of the use solution for 10 minutes at 20°C. Individual carriers were transferred to 10 mL of Fluid Thioglycollate Medium to neutralize. After 30-60 minutes, the carriers were transferred from primary subculture tubes into secondary subculture tubes containing 10 mL of Fluid Thioglycollate Medium. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for viability, neutralization confirmation, and carrier quantitation.

**4. MRID 461660-05 "The Evaluation of the Efficacy of Virkon S Against *Brucella abortus* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load," by Mary K. Bennett. Study conducted at ViroMed Laboratories, Inc. Study completion date – July 31, 1995.**

This study was conducted against *Brucella abortus* (ATCC 4315). Two lots (Lot Nos. 1698 and 2050) of the product, Virkon S, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A 1:100 use solution was prepared using 400 ppm AOAC synthetic hard water (titration results not provided). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-hour old suspension of the test organism. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to the use solution for 10 minutes at 20°C. Individual carriers were transferred to 10 mL of Universal Neutralizer Broth to neutralize. After 30-60 minutes, the carriers were transferred from primary subculture tubes into secondary subculture tubes containing 10 mL of Letheen Broth. All subcultures were incubated for 48 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for viability, neutralization confirmation, and carrier quantitation.

**5. MRID 461660-06 "10 Minute Inactivity of *Chlamydia psittaci* by Virkon S," by C. Sue Brady. Study conducted at ViroMed Laboratories, Inc. Study completion date – January 16, 1996.**

This study was conducted against *Chlamydia psittaci* (Strain 6 BC; ATCC VR-125), using McCoy cells (propagated in-house; originally obtained from ViroMed Laboratories, Inc., Cell Culture Division) as the host system. Two lots (Lot Nos. 1698 and 2050) of the product, Virkon S, were tested according to a ViroMed protocol (copy not provided). Fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. A use solution was prepared by adding 50 grams of the product to 5 liters of 400 ppm AOAC synthetic hard water (titrated at 401 ppm; a 1:100 dilution). Films of virus were prepared by spreading 0.2 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were kept at 23°C for 20 minutes, and then dried at 37°C for 30 minutes. For each lot of product, separate dried virus films were exposed to 2.0 mL of the use solution. The carriers remained exposed to the use solution for 10 minutes at 23°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was added to 18 mL of Letheen Broth with 0.1% sodium thiosulfate, and diluted serially in Eagles Minimal Essential Medium

supplemented with 10% fetal bovine serum and 10 µg/mL gentamicin. McCoy cells in multi-well culture dishes were inoculated in quadruplicate with 0.2 mL of the dilutions, spun at 4300 rpm for 60 minutes, and incubated at 36-37°C for 45 minutes. The inoculum was removed from all vials and replaced with 1 mL of test media. The cells were incubated for 48 hours and then examined microscopically for cytotoxicity followed by a fluorescent antibody assay. Controls included those for cytotoxicity, dried virus count, and "neutralization". Viral and cytotoxicity titers were calculated by the method of Karber.

**6. MRID 461660-07 "AOAC Use-Dilution Method" for Antec Virkon S, by Sally Nada. Study conducted at ATS Labs. Study completion date – May 6, 2003.**

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots (Lot Nos. 6168 and 6454) of the product, Virkon S, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A use solution was prepared by adding 1.2 g of the product to 118.8 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:100 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in a 54-hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to 10 mL of the use solution for 10 minutes at 20±1°C. Individual carriers were transferred to 10 mL of Universal Neutralizer to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C and then stored for one day at 2-8°C prior to examination. Following incubation and storage, the subcultures were then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

**7. MRID 461660-08 "The Evaluation of the Efficacy of Virkon S Against *Pseudomonas aeruginosa* and *Bacillus cereus* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load," by Mary K. Bennett. Study conducted at ViroMed Laboratories, Inc. Study completion date – January 6, 1997.**

This study was conducted against *Pseudomonas aeruginosa* (NCIMB 10421) and *Bacillus cereus* (ATCC 14579). Two lots (Lot Nos. 7347 and 2032) of the product, Virkon S, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A use solution was prepared by adding 50 g of the product to 5000 mL of 400 ppm AOAC synthetic hard water (titrated at 400.5 ppm for Lot No. 7347; titrated at 395.1 for Lot No. 2032; a 1:100 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to 10 mL of the use solution for 10 minutes at 20°C. Individual carriers were transferred to 10 mL of Universal Neutralizer with 1% Glycine to neutralize. After 30-60 minutes, the carriers were transferred from primary subculture tubes into secondary subculture tubes containing 10 mL of Letheen Broth. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for viability,

neutralization confirmation, and carrier quantitation.

**8. MRID 461660-09 "The Evaluation of the Efficacy of Virkon S Against *Shigella sonnei* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load," by Mary K. Bennett. Study conducted at ViroMed Laboratories, Inc. Study completion date – July 27, 1995.**

This study was conducted against *Shigella sonnei* (ATCC 25931). Two lots (Lot Nos. 1698 and 2050) of the product, Virkon S, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A 1:100 use solution was prepared using 400±4 ppm AOAC synthetic hard water (titration results not provided). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-hour old suspension of the test organism. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to the use solution for 10 minutes at 20°C. Individual carriers were transferred to 10 mL of Universal Neutralizer Broth to neutralize. After 30-60 minutes, the carriers were transferred from primary subculture tubes into secondary subculture tubes containing 10 mL of Letheen Broth. All subcultures were incubated for 48 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for viability, neutralization confirmation, and carrier quantitation.

**9. MRID 461660-11 "The Evaluation of the Efficacy of Virkon S Against *Trichophyton mentagrophytes* in the Presence of Hard Water and a 5% Soil Load," by Mary K. Bennett. Study conducted at ViroMed Laboratories, Inc. Study completion date – June 20, 1995.**

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot Nos. 1698 and 2050) of the product, Virkon S, were tested using the AOAC Use-Dilution Method (modified for fungi) as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. A use solution was prepared by adding 50 grams of the product to 2500 mL of 400 ppm AOAC synthetic hard water (titration results not provided; a 1:50 dilution). Ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in the conidial suspension of the test organism. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to the use solution for 10 minutes at 20°C. Individual carriers were transferred to 10 mL of Sabouraud Dextrose Broth to neutralize. Carriers were transferred from primary subculture tubes into secondary subculture tubes containing 10 mL of Sabouraud Dextrose Broth 30-60 minutes after the first transfer. All subcultures were incubated for 10 days at 30°C. The subcultures were examined for the presence or absence of visible growth. Controls included neutralization confirmation, viability, and carrier quantitation.

**10. MRID 461660-12 "Approval of Disinfectant – Antec Virkon S," by the Ministry of Agriculture, Fisheries and Food. Study conducted at The Institute for Animal Health. Study completion date – March 20, 1986. [A project number was not**

**provided.]**

This document presents a notice of approval from the Ministry of Agriculture, Fisheries and Food for the product, Antec Virkon S, as a disinfectant against Foot-and-mouth disease virus (at a 1:1300 dilution), Swine vesicular disease virus (at a 1:200 dilution), fowl pest virus (at a 1:280 dilution), and for use under "general orders" (at a 1:120 dilution).

This document also described various protocols and approval criteria. The document did not include test results or control data for the product, Virkon S.

Note: This study was not sponsored by Antec International Ltd. and consequently, Antec does not know whether it was conducted observing GLP standards as specified in 40 CFR Part 160.

**11. MRID 461660-13 "Laboratory Evaluation of ANTEC VIRKON S Disinfectant as a Virucidal Agent against Infectious Bursal Disease (Gumboro) Virus," by Dr. G. A. Cullen. Study conducted at Ministry of Agriculture, Fisheries and Food, Central Veterinary Laboratory. Study completion date – April 15, 1986. [A project number was not provided.]**

This study was conducted against Infectious bursal disease (Gumboro) virus (Strain 52/70, source not provided), using the bursae of SPF chickens as the host system. One lot (lot number not provided) of the product, Virkon S Powder, was tested using the protocol employed in approval of disinfectants against Fowl Pest, substituting the Infectious bursal disease virus. [A description of this protocol is provided in the document assigned MRID No. 461660-12.] A 1:250 use solution was prepared using hard water (target concentration of hard water not provided; titration results not provided). Controls were not identified, described, or discussed.

Note: According to the laboratory report, this study "was not originally intended for submission to US EPA and consequently Good Laboratory Practice Standards, as specified in 40 CFR Part 160, were not observed during its conduct."

**12. MRID 461660-14 "The Virucidal Effect of Virkon S on Chicken Anaemia Agent," by P. J. Wyeth. Study conducted at Ministry of Agriculture, Fisheries and Food, Central Veterinary Laboratory. Study completion date – March 13, 1990.**

This study was conducted against Chicken anaemia virus (Strain Cux 1, source not provided), using MDCC MSB1 cells (identification and source not specified) as the host system. One lot (lot number not provided) of the product, Virkon S, was tested using the "standard disinfectant test for viruses as approved by the [Ministry of Agriculture, Fisheries and Food (MAFF)], Weybridge (copy not provided)." Two use solutions (1:125 and 1:250) were prepared using hard water. Bakers yeast at 5% was added to the virus suspension. Each use solution was tested by adding 2.5 mL of the virus/yeast mixture to 2.5 mL of the use solution. Each

mixture was kept on ice for 30 minutes, and shaken every 10 minutes. The viral content was determined by titration in SPF chicks. The only control specified was viral stock titer.

Note: According to the laboratory report, this study "was not originally intended for submission to US EPA and consequently Good Laboratory Practice Standards, as specified in 40 CFR Part 160, were not observed during its conduct."

**13. MRID 461660-18 "Laboratory Evaluation of ANTEC 'Virkon S' Disinfectant as a Virucidal Agent against Avian Influenza Virus," by G. Parsons. Study conducted at Ministry of Agriculture, Fisheries and Food, Central Veterinary Laboratory. Study completion date – November 26, 1985. [A project number was not provided.]**

This study was conducted against Avian influenza virus (Strain A/Chicken/Germany/34 (H7N1); source not provided), using an unspecified host system. One lot (lot number not provided) of the product, Virkon S Powder, was tested according to the standard protocol used for approval of disinfectants against fowl pest but substituting the Avian influenza virus for Newcastle disease virus. [A description of this protocol is provided in the document assigned MRID No. 461660-12.] Use solutions of 1:280, 1:300, and 1:320 were prepared using hard water (target concentration of hard water not provided; titration results not provided). Testing appears to have been conducted in the presence of yeast. Controls included those for toxicity and dried virus count.

Note: According to the laboratory report, this study "was not originally intended for submission to US EPA and consequently Good Laboratory Practice Standards, as specified in 40 CFR Part 160, were not observed during its conduct."

**14. MRID 461660-19 "Virucidal Effectiveness Test" for Virkon S, by M. Khalid Ijaz. Study conducted at MicroBioTest, Inc. Study completion date – November 18, 2003. Laboratory Project Identification Number 517-101.**

This study was conducted against Porcine circovirus type II (strain not specified; obtained from American BioResearch Laboratories), using PT-1 cells (propagated in-house; originally obtained from American BioResearch Laboratories) as the host system. Two lots (Lot Nos. 10851 and 10650) of the product, Virkon S, were tested according to MicroBioTest Protocol "Virucidal Effectiveness Test, Porcine circovirus," dated July 25, 2003 (copy provided). A use solution was prepared by adding 1 gram of the product to 199 mL of 400 ppm AOAC synthetic hard water (titration results not provided; a 1:200 dilution). The stock virus culture contained at least a 5% organic soil load (serum not specified). Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at 25°C for 30-60 minutes. For each lot of product, separate dried virus films were treated with 2.0 mL of the use solution. The carriers remained exposed to the use solution for 10 minutes at 25°C. After exposure, the virus-disinfectant mixture was neutralized with 2.0 mL fetal bovine serum containing 0.3% sodium thiosulfate, and the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephacryl column, and diluted serially in Eagle's Minimum Essential Medium containing 10% fetal bovine serum. PT-1 cells in multi-well culture dishes were inoculated in quadruplicate with an unspecified amount of the dilutions. The cultures were incubated at

37±2°C in 5±1% $CO_2$ for 20-30 hours for viral adsorption. Post adsorption, the media was aspirated. Then, the monolayer was washed once with ~1 mL of cell culture medium, re-fed with 2 mL of cell culture medium, and returned to the above incubation conditions for 5-7 days. Post-incubation, the fluorescence focus forming units (FFFU) were scored. Controls included those for cell viability/sterility, cytotoxicity, plate recovery, column titer, virus stock titer, and neutralizer effectiveness. The 50% Fluorescent Focus Forming Unit Dose ($FFFUD_{50}$) per mL was determined by the method of Reed and Muench.

**15. MRID 462650-01 "Efficacy of Virkon-S Against SVCV," by Andrew E. Goodwin. Study conducted at University of Arkansas at Pine Bluff. Study completion date – October 6, 2003. [A project number was not provided.]**

This study was conducted against Spring Viremia of Carp virus (SVCV; Strain US; source not provided), using EPC cells (source not provided) as the host system. One lot (lot number not provided) of the product, Virkon S was tested using a non-carrier protocol similar to that used by APHIS at Plumb Island to test the efficacy of disinfectants against the Foot and mouth disease virus. The stock virus culture contained a 10% organic soil load (serum not specified). A suspension was prepared by adding 1 mL of tissue culture supernatant with SVCV to 8 mL of sterile WHO standard water with 1% fetal calf serum. Four use solutions of the product, Virkon S, were prepared to produce final concentrations of 1:100, 1:500, 1:1000 and 0:1000 w/v. A duplicate set was prepared with no viral load to control for cytotoxicity. The cultures were incubated at 4°C for 30 minutes. After incubation, aliquots were removed from the tubes and plated on 70% confluent monolayers of EPC cells in triplicate with Noble Agar overlays for 5 dilutions. The plates were incubated at 23°C and examined for unspecified cytopathic effects for 10 days.

As Plaque-Forming Unit (PFU) determinations under agar were not easy to interpret, a second trial was conducted as above. However, after incubation, aliquots were removed from the tubes and serially diluted in triplicate on EPC cells grown on 96-well plates. The plates were incubated at 23°C and examined for unspecified cytopathic effects for 10 days. Only a control for cytotoxicity was noted.

Note: According to the laboratory report, this study "was not originally intended for submission to US EPA and consequently Good Laboratory Practice Standards, as specified in 40 CFR Part 160, were not observed during its conduct."

**16. MRID 462650-02 "Virucidal Effectiveness Test" for Virkon S, by Gregory R. Dennis. Study conducted at MicroBioTest, Inc. Study completion date – August 24, 1991. Laboratory Project ID 178-102.**

This study was conducted against Calf rotavirus (ATCC VR-452), Transmissible gastroenteritis virus (ATCC VR-763), Parvovirus (ATCC VR-742), Parainfluenza virus (ATCC VR-281), Duck adenovirus (egg drop syndrome; ATCC VR-921), Infectious bovine rhinotracheitis virus (ATCC VR-188), Bovine viral diarrhea virus (ATCC VR-534), Pseudorabies virus (ATCC VR-135), Turkey herpes virus (TRT; ATCC VR-584-C), and Equine arteritis virus (ATCC VR-796). Chick embryo fibroblasts (ATCC CRL-1590), African green monkey kidney cells (ATCC CCL-81), Embryonic swine kidney cells (ATCC CCL-184), HeLa cells (ATCC CCL-2), Duck embryonic cells (ATCC CCL-141) and HeLa cells (ATCC CCL-2) were used as host

systems. Two lots (Lot Nos. 3133 and 3134) of the product, Virkon S, were tested according to a MicroBioTest protocol (copy not provided). A 1:100 use solution was prepared using deionized water. Heat-inactivated newborn calf serum was added to the stock virus cultures to achieve a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile Petri dishes. The virus films were air-dried for 20 minutes at ambient temperature. For each lot of product, separate dried virus films were treated with 2 mL of the use solution and allowed to remain wet for 10 minutes at 20°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was mixed 1:1 with neutralizer (not specified), and diluted serially in apparently Minimum Essential Medium. Host cells in multi-well culture dishes were inoculated in quadruplicate with an unspecified amount of the dilutions. The cultures were incubated at 37±1°C in 5±1% $CO_2$ for viral adsorption. Following adsorption, the cultures were aspirated, washed, and re-fed. The cultures were incubated at 37±1°C in 5±1% $CO_2$ and, after 5 days, scored for the presence or absence of unspecified cytopathic effects. Controls included those for virus stock titer and plate recovery. $CCID_{50}$/mL was calculated by the method of Reed and Muench.

Note: According to the laboratory report, this study "was not originally intended for submission to US EPA and consequently Good Laboratory Practice Standards, as specified in 40 CFR Part 160, were not observed during its conduct." However, the study was conducted in accordance with the FDA's Good Laboratory Practice regulation (21 CFR Part 58).

Note: The "Conclusions" section of the laboratory report incorrectly refers to a different product (i.e., Powder Detergent/Disinfectant) and different product lot numbers (i.e., Lot Nos. 1468-56 and 1468-57).

**17. MRID 462650-03 "Study Report on the Determination of Efficacy of Virkon S at Two Dilutions Against Three Isolates of *Mycoplasma mycoides* subspecies *mycoides* Small Colony Type Using the Hard Surface Carrier Test Method and In Use Test Method," by Dr. Roger Ayling. Study conducted at Veterinary Laboratories Agency. Study completion date – April 14, 2003. Contract Number UT1284.**

This study was conducted against three strains of *Mycoplasma mycoides* subspecies *mycoides* (Strains B103, Afadé, and NCTC Type 10114). One lot (Lot No. Bn9959) of the product, Virkon S, was tested using the AOAC Hard Surface Carrier Test Method and In Use Test Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. Two use dilutions (1:100 and 1:200) were prepared. Studies were conducted with no organic soil load and also in the presence of a 5% organic soil load (horse serum). Twenty (20) stainless steel penicylinder carriers per test were immersed for 15 minutes in a 24-48 hour old suspension of the test organism, at a ratio of 1 carrier per 42 mL broth. The carriers were dried for 40 minutes at 37°C. Each carrier was exposed to the use solution for 10 minutes at room temperature. Individual carriers were transferred to Eaton's medium containing 1% neutralizing solution to neutralize. All subcultures were incubated at 37°C and examined daily for 7 days for the presence or absence of visible growth. Controls included those for purity, neutralization confirmation, dried carrier counts, and confirmation of the challenge organisms.

Note: According to the laboratory report, this study "was not originally intended for submission

to US EPA and consequently Good Laboratory Practice Standards, as specified in 40 CFR Part 160, were not observed during its conduct."

**18. MRID 462650-04 "Test for Efficacy (Virkon S) Against African Swine Fever," by Stuart Williams. Study conducted at The Institute for Animal Health, Pirbright Laboratory. Study completion date – July 18, 2002. Project Number Dis P4/02.**

This study was conducted against African swine fever virus (Isolate LIL 20/1; source not specified), using pig bone marrow cells (PBM cells; source not specified) as the host system. One lot (Lot No. 6191) of the product, Virkon S, was tested according to a method designed by the Institute for Animal Health and adopted by the United Kingdom's Department for Environment, Food and Rural affairs (copy not provided). The stock virus culture contained a 1% organic soil load (fetal calf serum). The product was tested at dilution rates of 1:500, 1:600, 1:700 and 1:800 using 342 ppm WHO hard water as the diluent. For each use solution, 1 mL of the test organism and 1 mL of the use solution was added to 8 mL of sterile WHO hard water containing 1% fetal calf serum. Each mixture was held at 4°C for 30 minutes. After exposure, the virus-disinfectant mixtures were diluted serially in Phosphate Buffered Saline with 1% bovine serum. PBM cells in tubes were inoculated in triplicate with 1/3 mL (~0.33 mL) of the dilutions. The cultures were incubated at 37°C for 6 days and examined daily for haemadsorption. Positive cultures were those in which haemadsorbing (HAD) cells are present. Controls included a viral stock titer control, untreated control, and a positive control.

Note: According to the laboratory report, this study "was not originally intended for submission to US EPA and consequently Good Laboratory Practice Standards, as specified in 40 CFR Part 160, were not observed during its conduct."

## V RESULTS

Data in the following results tables are from testing of a 1:100 use solution unless otherwise noted.

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | Carrier Quantitation (CFU/ carrier) |
|---|---|---|---|---|
| | | Lot No. 9042 | Lot No. 10064 | |
| 461660-01 | *Escherichia coli* | 0/10 | 0/10 | $6.7 \times 10^6$ |
| 461660-01 | *Klebsiella pneumoniae* | 0/10 | 0/10 | $1.30 \times 10^7$ |
| 461660-01 | *Staphylococcus epidermidis* | 0/10 | 0/10 | $2.63 \times 10^6$ |
| 461660-01 | *Salmonella typhimurium* | 0/10 | 0/10 | $4.2 \times 10^6$ |
| 461660-01 | *Streptococcus pyogenes* | 0/10 | 0/10 | $7.5 \times 10^6$ |

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | Carrier Quantitation (CFU/ carrier) |
|---|---|---|---|---|
| | | Lot No. 2094 | Lot No. 2143 | |
| 461660-03 | *Staphylococcus aureus* | 0/10 | 0/10 | $1.31 \times 10^7$ |
| 461660-03 | *Salmonella choleraesuis* | 0/10 | 0/10 | $3.6 \times 10^6$ |

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | Carrier Quantitation (CFU/ carrier) |
|---|---|---|---|---|
| | | Lot No. 2032 | Lot No. 7347 | |
| 461660-04 | *Campylobacter jejuni* | 1° 0/10<br>2° 0/10 | 1° 0/10<br>2° 0/10 | $3.8 \times 10^6$ |
| | | Lot No. 1698 | Lot No. 2050 | |
| 461660-05 | *Brucella abortus* | 1° 0/10<br>2° 0/10 | 1° 0/10<br>2° 0/10 | $4.75 \times 10^6$ |
| 461660-09 | *Shigella sonnei* | 1° 0/10<br>2° 0/10 | 1° 0/10<br>2° 0/10 | $5.7 \times 10^5$ |
| | | Lot No. 6168 | Lot No. 6454 | |
| 461660-07 | *Listeria monocytogenes* | 0/10 | 0/10 | $1.86 \times 10^5$ |
| | | Lot No. 7347 | Lot No. 2032 | |
| 461660-08 | *Pseudomonas aeruginosa* (NCIMB 10421) | 1° 0/10<br>2° 0/10 | 1° 0/10<br>2° 0/10 | $9.7 \times 10^5$ |
| 461660-08 | *Bacillus cereus* | 1° 0/10<br>2° 0/10 | 1° 0/10<br>2° 0/10 | $3.1 \times 10^5$ |

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested (Lot Bn9959 + 5% serum) | | Carrier Quantitation (CFU/carrier) |
|---|---|---|---|---|
| | | 1:100 | 1:200 | |

| | | | | |
|---|---|---|---|---|
| 462650-03 | *Mycoplasma mycoides* subspecies *mycoides* (Strain NCTC) | No growth | No growth | $1.0 \times 10^{8*}$<br>$5.5 \times 10^{7**}$ |
| 462650-03 | *Mycoplasma mycoides* subspecies *mycoides* (Strain B103) | No growth | No growth | $3.6 \times 10^{5*}$<br>$2.5 \times 10^{6**}$ |
| 462650-03 | *Mycoplasma mycoides* subspecies *mycoides* (Strain Afadé) | No growth | No growth | $2.5 \times 10^{6*}$<br>$4.8 \times 10^{5**}$ |

*1:100 use dilution/**1:200 use dilution

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | Carrier Quantitation (CFU/carrier) |
|---|---|---|---|---|
| | | Lot No. 1698 | Lot No. 2050 | |
| 461660-11 | *Trichophyton mentagrophytes* (ATCC 9533)<br><br>(A 1:50 use solution was tested.) | 1° 0/10<br>2° 0/10 | 1° 0/10<br>2° 0/10 | $1.4 \times 10^5$ |

| MRID Number | Organism | Results | | | Dried Virus Control (or Plate Recovery) |
|---|---|---|---|---|---|
| 461660-06 | *Chlamydia psittaci* | | Lot No. 1698 | Lot No. 2050 | $10^{6.0}$ $TCID_{50}$/ 0.2 mL |
| | | $10^{-2}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | |
| | | $TCID_{50}$/0.2 mL | $\leq 10^{1.5}$ | $\leq 10^{1.5}$ | |
| | | | Lot No. 10851 | Lot No. 10650 | |
| 461660-19 | Porcine circovirus type II (A 1:200 use solution was tested.) | $10^{-3}$ to $10^{-7}$ dilutions | Complete inactivation | Complete inactivation | $10^{5.67}$ $FFFUD_{50}$/mL |
| | | $FFFUD_{50}$/mL | $\leq 10^{1.5}$ | $\leq 10^{1.5}$ | |
| 461660-13 | Infectious bursal disease (Gumboro) virus (A 1:250 use solution was tested.) | | Lot number not provided | | $10^{4.63}$ [units not specified] |
| | | Viral titer | $10^{0.5}$ | — | |
| 461660-14 | Chicken anaemia virus (A 1:125 use solution) | | Lot number not provided (1:125) | Lot number not provided (1:250) | $10^{5.5}$ $TCID_{50}$ |
| | | $TCID_{50}$ | $10^{0.15}$ | $10^{0.5}$ | |
| | | Log reduction | 5.35 $\log_{10}$ | 5.00 $\log_{10}$ | |

| | | | | | |
|---|---|---|---|---|---|
| 461660-18 | Avian influenza virus<br>(1:280, 1:300, and 1:320 use solutions were tested.) | | Lot number not provided | | $10^{4.06}$ $EID_{50}$ |
| | | $10^{-1}$ to $10^{-7}$ dilutions | Complete inactivation | | |
| | | $EID_{50}$ | $\leq 10^{0.5}$ | | |
| 462650-01 | Spring Viremia of Carp virus (1:100) | | Lot number not provided | | >$10^5$ PFU/mL |
| | | | Cytotoxicity observed for the 1:100 use solution is most likely due to product toxicity to cell monolayers. | | |
| | | | Lot No. 3313 | Lot No. 3314 | |
| 462650-02 | Calf rotavirus | $10^{-1}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | $4.7 \times 10^3$ $CCID_{50}$/mL |
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-02 | Transmissible gastroenteritis virus | $10^{-1}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | $4.7 \times 10^3$ $CCID_{50}$/mL |
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-02 | Parvovirus | $10^{-1}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | $3.2 \times 10^3$ $CCID_{50}$/mL |
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-02 | Parainfluenza virus | $10^{-1}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | $4.7 \times 10^4$ $CCID_{50}$/mL |
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-02 | Duck adenovirus | $10^{-1}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | $3.2 \times 10^3$ $CCID_{50}$/mL |
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-02 | Infectious bovine rhinotracheitis virus | $10^{-1}$ to $10^{-6}$ dilutions | Complete Inactivation | Complete inactivation | $4.7 \times 10^3$ $CCID_{50}$/mL |
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-02 | Bovine viral diarrhea virus | $10^{-1}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | $1.0 \times 10^4$ $CCID_{50}$/mL |
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-02 | Pseudorabies virus | $10^{-1}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | $1.0 \times 10^4$ $CCID_{50}$/mL |

| | | | | | |
|---|---|---|---|---|---|
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-02 | Turkey herpes virus | $10^{-1}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | $1.0 \times 10^4$ $CCID_{50}$/mL |
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-02 | Equine arteritis virus | $10^{-1}$ to $10^{-6}$ dilutions | Complete inactivation | Complete inactivation | $1.0 \times 10^4$ $CCID_{50}$/mL |
| | | $CCID_{50}$/mL | <10 | <10 | |
| 462650-04 | African swine fever virus (1:500, 1:600, 1:700, and 1:800 use solutions were tested) | | Lot No. 6191 | | $10^{5.75}$ $HAD_{50}$/mL |
| | | $10^{-1}$ to $10^{-7}$ dilutions | Not provided | | |
| | | $HAD_{50}$/mL | $\leq 10^{1.0}$ | | |
| | | Log reduction | $\geq 4.75$ $\log_{10}$ for each dilution | | |

Note: All three use solutions tested against Avian influenza virus had the same test results (i.e., complete inactivation).

Note: Results from studies conducted against Spring Viremia of Carp virus using 1:500, 1:1000, and 0:1000 (w/v) use solutions are available in the laboratory report assigned MRID No. 462650-01.

Note: All four use solutions tested against African swine fever virus had the same test results (i.e., showed the same reduction in titer).

## VI CONCLUSIONS

### A. Conclusions for Efficacy Studies Against Bacteria and Fungi

1. The submitted confirmatory efficacy data support the use of the tablet form of the product, Virkon S, as a broad-spectrum disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (fetal bovine serum) for contact time of 10 minutes at a 1:100 use dilution:

| | |
|---|---|
| *Salmonella choleraesuis* | MRID No. 461660-03 |
| *Staphylococcus aureus* | MRID No. 461660-03 |

No growth was observed in the subcultures of the carriers tested against two lots of the product. Dried carrier counts were at least $10^4$. Neutralization confirmation testing showed positive growth of the organisms. Viability controls were positive for growth. Purity controls were reported as pure, and sterility controls did not show growth.

2. The submitted efficacy data support the use of the product, Virkon S, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (fetal bovine serum) for a contact time of 10 minutes at a 1:100 dilution:

| | |
|---|---|
| *Bacillus cereus* | MRID No. 461660-08 |
| *Brucella abortus* | MRID No. 461660-05 |
| *Campylobacter jejuni* | MRID No. 461660-04 |
| *Escherichia coli* | MRID No. 461660-01 |
| *Klebsiella pneumoniae* | MRID No. 461660-01 |
| *Listeria monocytogenes* | MRID No. 461660-07 |
| *Pseudomonas aeruginosa* (NCIMB 10421) | MRID No. 461660-08 |
| *Salmonella typhimurium* | MRID No. 461660-01 |
| *Staphylococcus epidermidis* | MRID No. 461660-01 |
| *Streptococcus pyogenes* | MRID No. 461660-01 |
| *Shigella sonnei* | MRID No. 461660-09 |

No growth was observed in the subcultures of the carriers tested against the two product lots. Dried carrier counts were at least $10^4$. Neutralization confirmation testing showed positive growth of the organisms. Viability controls were positive for growth. When reported, purity controls were reported as pure, and sterility controls did not show growth.

3. The submitted efficacy data (MRID No. 462650-03) do not support the use of the product, Virkon S, as a disinfectant against ***Mycoplasma mycoides* subspecies *mycoides*** on hard, non-porous surfaces in the presence of a 5% organic soil load (horse serum) for a contact time of 10 minutes at a 1:100 dilution and 1:200 dilution. Dried carriers counts were at least $10^4$. Although no growth was observed in the subcultures, only one product lot was tested thus not satisfying the requirements set forth by DIS/TSS-1. Furthermore, GLP was not followed. Finally, label claims for efficacy at 400 ppm synthetic hard water were not substantiated by the submitted data.

4. The submitted efficacy data (MRID No. 461660-11) support the use of the product, Virkon S, as a disinfectant with fungicidal activity against ***Trichophyton mentagrophytes*** on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (fetal bovine serum) for a contact time of 10 minutes at a use dilution of 1:50. No growth was observed in any subcultures of the carriers tested against the two product lots. Neutralization confirmation testing showed positive growth of the organism. Viability controls were positive for growth. Dried carrier counts were at least $10^4$, which is consistent with the Agency's interim policy. [ For more details about this interim policy, see Section III of this efficacy report.]

5. The submitted efficacy data (MRID No. 461660-06) do not support the use of the product, Virkon S, as a disinfectant against ***Chlamydia psittaci*** on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (serum) for a contact time of 10 minutes at a 1:100 dilution. Neutralizer effectiveness testing was not conducted, to determine if residual active ingredients are present after neutralization. Neutralization effectiveness is determined by the following procedure: One lot of the test agent is used for the neutralizer effectiveness control. This control will be processed exactly as the test procedure but instead

of the inoculum, balanced salt solution is added. Post test, and neutralization, a 1.0 mL sample is divided into two portions, one for cytotoxicity and the other for neutralizer effectiveness. The neutralized sample is serially diluted in balanced salt solution and the test organisms will be added to each dilution and incubated for a period equivalent to the contact time. These samples are then used to inoculate host cells.

**B. Conclusion Regarding Studies Against Viruses**

1. The submitted efficacy data (MRID No. 461660-19) support the use of the product, Virkon S, as a disinfectant with virucidal activity against **Porcine circovirus type II** on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (serum) for a contact time of 10 minutes at a 1:200 dilution. Complete inactivation (no growth) was indicated in all dilutions tested. Cytotoxicity was not observed. A recoverable titer of at least $10^4$ was observed.

2. For approval of higher dilution rates (MRID No. 461660-12) against **Classical swine fever virus**, **Foot and Mouth Disease virus**, **Marek's Disease virus**, **fowl pest**, general orders and **Newcastle virus** are not acceptable due to the lack of efficacy data. The data package submitted was a proposal of potential studies, with no efficacy data. Until the proper efficacy data is submitted to satisfy the higher dilution rates, the use of the product, Virkon S, as a disinfectant against the listed microorganisms is not supported.

2. The submitted efficacy data (MRID No. 461660-13) do not support the use of the product, Virkon S, as a disinfectant against **Infectious bursal disease (Gumboro) virus** on hard, non-porous surfaces at a dilution of 1:250, due to the following deficiencies:

(a) No contact time was included in the study;
(b) Only one product lot was tested, not the required two;
(c) The soil load was not specified;
(d) The target concentration of hard water was not provided;
(e) Test results for each replication were not provided per DIS/TSS-3; only a narrative summary of the test results was provided;
(f) It is unclear whether four determinations per each dilution were assayed;
(g) Neutralizer effectiveness testing does not appear to have been conducted;
(h) GLP was not followed; the study was conducted in 1986.

3. The submitted efficacy data (MRID No. 4616660-14) do not support the use of the product, Virkon S, as a disinfectant against **Chicken anemia virus** on hard, non-porous surfaces at use dilutions of 1:125 and 1:250, due to the following deficiencies:

(a) A 30 minute contact time, with agitation every 10 minutes was used in the test protocol, however the label specified a 10 minute contact time;
(b) Only one product lot was tested, not the required two;
(c) The purpose of Baker's yeast was not specified;
(d) The target concentration of the hard water used during testing was not provided;
(e) Test results for each replication were not provided per DIS/TSS-3
(f) It is unclear whether four determinations per each dilution were assayed;

(g) Neutralizer effectiveness testing does not appear to have been conducted;
(h) GLP was not followed; study was conducted in 1990.

4. The submitted efficacy data (MRID No. 461660-18) do not support the use of the product, Virkon S, as a disinfectant against **Avian influenza virus** on hard, non-porous surfaces at use dilutions of 1:280, 1:300, and 1:320, due to the following deficiencies:

(a) Only one product lot was tested, not the required two
(b) The soil load was not specified;
(c) The target concentration of the hard water used during testing was not provided;
(d) It does not appear that four determinations per each dilution were assayed;
(e) Neutralizer effectiveness testing does not appear to have been conducted;
(f) GLP was not followed; the study was conducted in 1985
(g) Data submitted for Avian influenza virus is to be used as a substitute for Newcastle disease virus. The Agency has not determined if Avian influenza virus is a surrogate for Newcastle disease virus. Avian influenza virus is classified in the family of viruses labeled Orthomyxoviridea, while Newcastle disease is classified in the family of viruses labeled Paramyxoviridea. Although both families of viruses are single-stranded RNA viruses, there exist some substantial differences that cannot be overlooked.

5. The submitted efficacy data (MRID No. 462650-01) do not support the use of the product, Virkon S, as a disinfectant against **Spring Viremia of Carp virus** on hard, non-porous surfaces at use dilutions of 1:100, 1:500, 1:1000, and 1:2500, due do the following deficiencies,

(a) Only one product lot was tested, not the required two;
(b) The test protocol did not include a neutralization step;
(c) GLP was not followed; the study was conducted in 2003;
(d) A 30-minute contact time was used during testing, not the labeled-specified 10 minutes;
(e) The recommended use-dilution is unclear from the present data. CPE observed at the 1:100 dilution, is not represented of efficacy. In the Conclusion section of the data report, it is stated that "additional work should be done to further replicate these results. More importantly, additional trials should be conducted at a Virkon-S concentration of 1:250 ..."

6. The submitted efficacy data (MRID No. 462650-02) do not support the use of the product, Virkon S, as a disinfectant against **Calf rotavirus**, **Duck adenovirus**, **Infectious bovine rhinotracheitis virus**, **Parvovirus**, **Parainfluenza virus**, **Bovine diarrheal diarrhea virus**, **Equine arteritis**, **Pseudorabies**, **Turkey Herpes virus** and **Transmissible gastroenteritis virus** on hard, non-porous surfaces at use dilutions of 1:100, due to the following deficiencies,

(a) Neutralizer effectiveness testing (where a low level of virus is added);
(b) Cytotoxicity was not conducted or reported;
(c) GLP was not followed; study was conducted in 1991;
(d) Testing was not conducted using 400 ppm synthetic water, therefore the label must to modified to reflect change;
(e) The Conclusions section of the laboratory report refers to a different product (i.e., Powder Detergent/Disinfectant) and different product lot numbers (i.e., Lot Nos. 1468-

56 and 1468-57). The appropriate conclusions should be submitted to correct the efficacy study;
(f) According to DIS/TSS-7, disinfectants must be tested against a recoverable titer of at least $10^4$ from the test surfaces. Viral titers for Calf rotavirus, Transmissible gastroenteritis virus, Parvovirus, Duck adenovirus (Egg Drop syndrome), Infectious bovine rhinotracheitis virus (ranged from $3.2 \times 10^3$ to $4.7 \times 10^3$ $CCID_{50}$/mL).

7. The submitted efficacy data (MRID No. 462650-04) do not support the use of the product, Virkon S, as a disinfectant against **African swine fever virus** on hard, non-porous surfaces at use dilutions of 1:500, 1:600, 1:700, and 1:800, due to the following deficiencies,

(a) Only one product lot was tested, not the required two;
(b) The product was tested in the presence of a 1% organic soil load, not a 5% organic soil load;
(c) The product was tested in the presence of 342 ppm hard water, not 400 ppm hard water;
(d) Test results for each replication were not provided, per DIS/TSS-3.
(e) Three determinations per each dilution were assayed, not the required four.
(f) The test protocol did not include a neutralization step;
(g) GLP was not followed; the study was conducted in 2002;
(h) A 30-minute contact time was used during testing, not the label-specified 10 minutes.

## VII RECOMMENDATIONS

### A. Label Claims supported by the Applicant's Data

1. The proposed label claims are acceptable regarding the use of the product, Virkon S, – now also in tablet form– as a broad-spectrum disinfectant on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic material when used for a contact time of 10 minutes at a 1:100 dilution, as supported by the submitted data.

2. The proposed label claims are acceptable regarding the use of the product Virkon S, as a disinfectant on hard, non-porous surfaces in the presence of 400 ppm hard water and 5% organic material when used for a contact time of 10 minutes at a 1:100 dilution against the following microorganisms, as supported by the applicant's data:

*Brucella abortus*
*Bacillus cereus*
*Campylobacter jejuni*
*Listeria monocytogenes*
*Shigella sonnei*
*Escherichia coli*
*Klebsiella pneumoniae*
*Pseudomonas aeruginosa*
*Staphylococcus aureus*
*Streptococcus pyogenes*
*Salmonella typhimurium*
*Salmonella choleraesuis*

3. The proposed label claims are acceptable for the use of the product, Virkon S, as a disinfectant against **Porcine circovirus type II** on hard, non-porous surfaces in the presence 400 ppm hard water and 5% organic material when used for a contact time of 10 minutes at a use dilution of 1:200.

4. The proposed label claims are acceptable regarding the use of the product, Virkon S, as a disinfectant with fungicidal properties against ***Trichophyton mentagrophytes*** on hard, non-porous in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at 1:50 use dilution, as supported be the submitted efficacy data. The contact time and use dilution rates are consistent with the proposed label claims. The applicant should specify on the proposed label, page 5, Broad Spectrum Disinfectant, that efficacy against *Trichophyton mentagrophytes* was demonstrated at 2% use dilution, not the insinuated 1% solution in mentioned in this section. This is clarified on page 12, Institutional and Service Facilities (Human Health) section on the proposed label. For clarity, the use dilution should be mentioned in both areas of the proposed label.

5. The proposed label claims do support the use of the product, Virkon S, as a disinfectant on hard, non-porous surfaces against ***Xanthomonas axonopodis*** and **Mouse Parvovirus**. Neither *Xanthomonas axonopodis* nor Mouse Parvovirus are considered pests according to the OIE, therefore efficacy data is not required at this time. A use dilution and contact time should be included on the proposed label. At present it is unclear, as to what use dilutions and contact times ensure efficacy.

**B. Label claims Not Supported Because of Deficient Information**

1. The proposed label claims that the product, Virkon S, is a disinfectant on hard, non-porous surfaces in the presence of 400 ppm hard water and 5% organic material when used for a contact time of 10 minutes at a 1:100 dilution against the following microorganisms:

*Chlamydia psittaci*
Spring Viremia of carp virus

These claims are not supported by the applicant's data. As detailed in the Conclusions section of this report, the data provided by the applicant was deficient and did not meet Agency standards. Furthermore the recommended use dilution for Spring Viremia of Carp virus is not clear on the proposed label. From the submitted efficacy report, CPE observed at 1:100 was due to toxicity of Virkon-S. The applicant should remove claims that reference the unaccepted studies from the proposed label, or provide the necessary efficacy that fully meet Agency standards.

2. The proposed label claims that the product, Virkon S, is a disinfectant at higher dilution rates for the following microorganisms:

African swine fever virus (at a 1:800 dilution)
Chicken anemia virus (at a 1:250 dilution)
Avian influenza virus (at a 1:312 dilution)
Infectious bursal disease virus (at a 1:250)

Transmissible gastroenteritis virus (at a 1:450 dilution)
*Mycoplasma mycoides* (at a 1:200 dilution)

These claims are not supported by the applicant's data. The applicant needs to remove these claims from the proposed label, or provide efficacy data that fully meet Agency standards.

3. The proposed label claims that the product, Virkon S, is a disinfectant at higher dilution rates for the following microorganisms:

Classical swine fever virus (at a 1:150 dilution)
Foot and mouth disease virus (at a 1:1300)
Marek's disease virus (at a 1:200 dilution)
Newcastle disease virus (at a 1:280 dilution)
Swine vesicular disease virus (at a 1:200 dilution)

These claims are not supported. The applicant did not provide efficacy data to support these claims. The applicant needs to remove these claims from the proposed label, or provide the necessary efficacy data to comply with Agency standards.

Note: The laboratory report assigned MRID No. 461660-12 states that the product, Virkon S, is approved as a disinfectant against Foot and Mouth disease virus (1:1300 dilution) and against Swine vesicular disease virus (at a 1:200 dilution); however, the laboratory report did not include test results or control data.

**C. Miscellaneous Recommendations**

1. The proposed label continues to claim effectiveness against *Candida albicans* [see page 5 and 12 of the proposed label; Human Health Pathogens section and Institutional and Service Facilities section, respectively], although the applicant said that such claims have been removed. The applicant should comply with removal of the claims against *Candida albicans*.

2. The applicant should make the following changes to the proposed label, as appropriate:

- On page 8, change "Maraxella bovis" to read Moraxella bovis."
- On page 10, change "Foot and Mouse Disease Virus" to read "Foot and Mouth Disease Virus."
- On the page 12, change "or other textiles only it area is tested" to read "or other textiles only if area is tested."

3. On page 5 of the proposed label, under the section Broad Spectrum Disinfectant, there are ambiguous statements that need to be clarified. Briefly the statement , "Virkon S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. . . . Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm AOAC hard water and 5% organic material," is misleading. As mentioned in the Conclusion section, several studies were

unclear concerning the final concentration of hard water and the presence/absence of organic material. This statement should be corrected to reflect only the microorganisms that were subjected to the stated test conditions (400 ppm and organic material). Furthermore, some of the test conditions required greater than 1% solution to demonstrate efficacy (i.e, *Trichophyton mentagrophytes*), again making the statement listed above inaccurate and ambiguous.

4. Special instructions are required when claims against Human Immunodeficiency Virus (HIV) are proposed. An example of these special instructions is listed below:

> **Special Instructions for Cleaning and Decontamination Against HIV-1 on hard, non-porous surfaces/objects soiled with blood/body fluids."**
>
> **Personal Protection**: Clean-up should always be done wearing protective latex gloves, gowns, masks, and eye-protection.
>
> **Cleaning Procedure**: Blood and other body fluids containing HIV-1 must be thoroughly cleaned from surfaces and objects before application of [product].
>
> **Disposal of Infectious Materials**: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Note to PM– I caution the Agency against approving multiple use dilutions and contact times for microorganisms. This product has been granted approval previously, with varying use dilutions for viruses and bacteria. Oft times when a product is used, a consumer is unaware of the microbial contamination and possible interactions between multiple contaminants. For it is rare that a surface is consistently contaminated with one species. Antec's rationale is that "Virkon S is used for specific known disease outbreaks."

Antec™
INTERNATIONAL
A DuPont Company

July 16, 2004

Document Processing Desk (COADR)
US Environmental Protection Agency
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

To Whom It May Concern:

Subject: Addition of Non-Exclusive Agent
Antec International EPA Company No. 62432 – /

This letter is to confirm the appointment of the following non-exclusive agent to act on behalf of Antec International in all matters related to US EPA registration activities. Antec International is now a subsidiary of the DuPont Company. The US Environmental Protection Agency is authorized to discuss all matters, including Confidential Business Information, with the appointed agent.

Nancy Lomax
Regulatory Manager
Dupont Chemical Solutions Enterprise
P. O. Box 80023
Wilmington, DE 19880-0023
Phone (302) 892-8268

Should you have any question, please feel free to call.

Sincerely,

Mark Squire
Chief Chemist

CC: Mr. Jeff Jones, Delta Analytical Corp

should not be on CNA response 8/4/04

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 9, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DELTA ANALYTICAL CORPORATION
ANTEC INTERNATIONAL LTD
7910 WOODMONT AVENUE, #1000
BETHESDA, MD 20814

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 05-MAY-04 Our staff has completed a preliminary analysis of the material The results are provided as follows.

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5 A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted Please use these numbers in all future references to these documents. Thank you for your cooperation If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

DELTA
ANALYTICAL
CORPORATION

January 5, 2004

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Your Letters Dated July 22, 2003, and August 5, 2003; New Alternate Formulas; Addition of Organism Claims; Higher Dilution Rates

Dear Adam:

The purpose of this submission is to respond to your letter of July 22 regarding Reregistration requirements, to respond to your letter of August 5 regarding the Spring Viremia of Carp claim, to propose a new basic and several alternate formulas, to add organism claims, and to specify higher dilution rates when specific organisms are targeted. The submission includes:

- Application for Pesticide Registration (EPA Form 8570-1)
- Confidential Statement of Formulas (EPA Form 8570-4; 2 copies)
- Proposed Product Label (5 copies); one copy with proposed changes highlighted
- Current Stamped Label
- Certification with Respect to Citation of Data and Data Matrix (EPA Form 8570-34 and 8570-35)
- Response to Comments in EPA Letter Dated July 22, 2003

The additional required data included in this package are submitted with separate cover letters depending on the purpose of the data submission.

Response to July 22, 2003 Reregistration Letter

In the July 22, 2003, letter following the reregistration review of the Virkon S registration, the Agency requested certain changes in precautionary and first aid statements, and questioned certain organism claims based on previously submitted data. An attachment to this letter, "Response to Comments in EPA Letter Dated July 22, 2003" address each of the Agency's comments in turn. This submission contains requested label changes and in some cases new data addressing organism claim issues.

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814
(301) 652-5495 FAX (301) 652-5408

Spring Viremia of Carp Claim

In your letter of August 5, 2003, you denied the proposed label claim against Spring Viremia of Carp because it is a "public health organism." While I believe the Agency is now convinced it is not a public health organism, I note that it is present on OIE List B. This submission includes the requested efficacy data in the package with data supporting new organism claims.

Replacement Basic Formula

The replacement basic formula corrects the original and current approved formula whose active ingredient percentage was based on the lower certified limit rather than the nominal value. This brings the Virkon S active ingredient percentage for potassium peroxymonosulfate more in line with the Virkon formula (EPA Reg. No. 62432-2). I will be submitting a replacement basic formula for Virkon shortly which is absolutely consistent with the new basic formula for Virkon S. I emphasize that these replacement basic formulas involve no change in the formulation whatsoever, but simply accurately reflect the nominal value for potassium peroxymonosulfate and improved accuracy in the active ingredient percentage calculation.

New Alternate Formulas

The proposed alternate formulas include dye and fragrance-free variations on the basic formula and a new tablet formula. The tablet formula is supported by confirmatory efficacy data which is attached.

New Organism Claims

The proposed label includes new organism claims against *Bacillus cereus, Brucella abortus, Campylobacter jejuni, Chlamydia psittaci, Listeria monocytogenes, Shigella sonnei,* Spring Viremia of Carp Virus, Swine Vesicular Disease Virus, and Trichophyton mentagrophytes. Data supporting these claims is submitted herein. The data on Swine Vesicular Disease is included in the data package for higher dilution rates discussed below.

A new animal health claim against Mouse Parvovirus and a new plant pathogen claim against *Xanthomonas axonopodis* are also proposed in this submission. Supporting efficacy data for these claims has not been submitted but is available for submission.

Higher Dilution Rates

The proposed label includes a new use pattern titled "Disinfection Limited to Specific and Known Disease Organisms." For general disinfection, the recommended application

rate calls for a 1% solution. When Virkon S is used for a specific and known disease outbreak, Antec would like to recommend higher dilutions (weaker solutions). Data evaluating Virkon S efficacy at the proposed dilution rates are included in this submission.

If you have questions about this submission or need additional documents or clarification, please contact me.

Thanks for your assistance.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd.

Enclosures

DELTA
ANALYTICAL
CORPORATION

December 21, 2003

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Efficacy Data Responding to Agency Comments in Letter Dated July 22, 2003**

Dear Adam:

Enclosed please find the following data submitted in response to the Agency's comments in a letter dated July 22, 2003:

- Volume 1 of 1
  AOAC Use-Dilution Method: *Escherichia coli, Klebsiella pneumoniae, Staphylococcus epidermidis, Salmonella typhimurium* and *Streptococcus pyogenes*; Antec Virkon S.
  MRID# 46166001

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd.
Enclosures

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814
(301) 652-5495 FAX (301) 652-5408

DELTA
ANALYTICAL
CORPORATION

December 21, 2003

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Confirmatory Efficacy Data Submission for Tablet Formulation**

Dear Adam:

Enclosed please find the following data submitted to support new tablet formuation:

- Volume 1 of 2
  Product Chemistry: Supplement to Manufacturing Process Description; Virkon S Tablets
  MRID# 46166002

- Volume 2 of 2
  AOAC Use-Dilution Method: *Staphylococcus aureus* (ATCC 6538) and *Salmonella cholerasuis* (ATCC 10708)
  MRID# 46166003

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd.
Enclosures

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814
(301) 652-5495 FAX (301) 652-5408

DELTA
ANALYTICAL
CORPORATION

December 21, 2003

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Data Submission to Support New Organism Claims**

Dear Adam:

Enclosed please find the following data submitted in support of new organism claims on the Virkon S label:

- Volume 1 of 8
  The Evaluation of the Efficacy of Virkon S against *Campylobacter jejuni* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load
  MRID# 46166004

- Volume 2 of 8
  The Evaluation of the Efficacy of Virkon S against *Brucella abortus* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load
  MRID# 46166005

- Volume 3 of 8
  10 Minute Inactivation of *Chlamydia psittaci* by Virkon S
  MRID# 46166006

- Volume 4 of 8
  AOAC Use-Dilution Method: *Listeria monocytogenes* (ATCC 19117)
  MRID# 46166007

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(301) 652-5495 FAX (301) 652-5408

- Volume 5 of 8
  The Evaluation of the Efficacy of Virkon S against *Pseudomonas aeruginosa* and *Bacillus cereus* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load
  MRID# 46166008

- Volume 6 of 8
  The Evaluation of the Efficacy of Virkon S against *Shigella sonnei* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load
  MRID# 46166009

- Volume 7 of 8
  Efficacy of Virkon-S against SVCV
  MRID# 46285001

- Volume 8 of 8
  The Evaluation of the Efficacy of Virkon S against *Tricophyton mentagrophytes* in the Presence of Hard Water and a 5% Soil Load
  MRID# 46166011

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd.
Enclosures

DELTA
ANALYTICAL
CORPORATION

December 21, 2003

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Efficacy Data to Support Higher Dilution Rates**

Dear Adam:

Enclosed please find the following data submitted to support the higher dilution rates (weaker solutions) on the Virkon S directions for use:

- Volume 1 of 8
  Ministry of Agriculture, Fisheries and Food: Approval of Disinfectants-Antec Virkon S
  MRID# 46166012

  [This study was previously reviewed in conjunction with the Agency's approval of the Foot and Mouth Disease claim several years ago.]

- Volume 2 of 8
  Laboratory Evaluation of Antec Virkon S Disinfectant as a Virucidal Agent against Infectious Bursal Disease (Gumboro) Virus
  MRID# 46166013

- Volume 3 of 8
  The Virucidal Effect of Virkon S on Chicken Anaemia Agent
  MRID# 46166014

- Volume 4 of 8
  Virucidal Effectiveness Test
  MRID# 46265002

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(301) 652-5495 FAX (301) 652-5408

- Volume 5 of 8
  The Determination of Efficacy of Virkon S at Two Dilutions against Three Isolates of *Mycoplasma mycoides subspecies mycoides* small colony type using the Hard Surface Carrier Test Method and in Use Test Method
  MRID# **46265003**

- Volume 6 of 8
  Test for Efficacy (Virkon S) against African Swine Fever
  MRID# **46265004**

- Volume 7 of 8
  Laboratory Evaluation of Antec 'Virkon S' Disinfectant as a Virucidal Agent against Avian Influenza Virus
  MRID# **46166018**

- Volume 8 of 8
  Virucidal Effectiveness Test; Porcine circovirus; Test Agent: Virkon S
  MRID# **46166019**

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd.
Enclosures

## Response to EPA Comments Pertaining to Reregistration in Letter Dated July 22, 2003

EPA Comment:

This product meets the criterion for Restricted Use Classification (RUP) based on the data that placed it in "Toxicity Category I" for primary eye irritation and primary dermal irritation categories. In lieu of classifying the subject product for RUP, the precautionary statement must be revised to read as follows:

PRECAUTIONARY STATEMENT
HAZARD TO HUMANS AND DOMESTIC ANIMALS
DANGER

Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). 'Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet remove contaminated clothing and wash clothing before reuse.

Antec Response:

The proposed label has been altered as EPA requested.

EPA Comment:

The Spanish signal word ***"PELIGRO"*** must be added to the keep out of reach of children statement.

Antec Response:

The Spanish signal word has been added to the proposed label.

EPA Comment:

The First Aid statement must read as follows: ....

Antec Response:

The format of the First Aid Statement has been altered as EPA requested.

EPA Comment:

The label claims are acceptable regarding the use of a 1% solution of the product, Virkon S, as cleaner-disinfectant against *Pseudomanas aeruginosa, Staphylococcus aureus,* and *salmonella choleraesuis* in the presence of hard water and organic material on hard nonporous surfaces for a contact time of 10 minutes. However the label must identify the concentration of hard water or organic soil loading.

Antec Response:

The current approved label identifies the "concentration of hard water or organic soil loading" as follows: "Efficacy of the 1% solution was determined in the presence of 400 ppm AOAC hard water and 5% organic material."

EPA Comment:

The label claims against *Campylobacter pylorodis* are acceptable. However, more information must be provided on the strain used in the study of *Campylobacter pylorodis* The strain was identified only by the testing laboratory's in-house ID number ("GBL"), and the characteristics of that strain are not known. Note also that the *Campylobacter pylorodis* tested was probably Campylobacter pylori, and is now called Helicobacter pylori.

Antec Response:

The label claim against *Campylobacter pyloridis* has been changed to *Helicobacter pylori.*

EPA Comment:

The label claims are not currently acceptable regarding the use of 1% solution of the product, Virkon S as a disinfectant against *Escherichia coli, KIebsiella pneumoniae, Staphylococcus epidermidis, Streptococcus pyo genes, Salmonella typhimurium and Candida albicans* in the presence of 400 ppm hard water on hard, non-porous surfaces for a contact time of 10 minutes. Although no growth was observed in subcultures of the carriers tested, the studies were not conducted in the presence of an organic soil load. Page 4 of the label indicates that product "efficacy was determined in the presence of hard water and organic material." Therefore, you must provide information that clarifies whether the 1989 studies or any other studies were conducted in the presence of an organic soil load against the above listed microorganisms.

Antec Response:

Antec has conducted new studies on each of the organisms identified by the Agency except *Candida albicans* in the presence of 400 ppm AOAC hard water and 5% soil load. The data is

submitted with this package for EPA review. The *Candida albicans* claim has been removed from the proposed label.

EPA Comment:

The label include claims of effectiveness against Humanimmunodificiency Virus (HIV), however, the data submitted did not include studies to confirm the claims of effectiveness against HIV for a contact time of minutes (or until air -dried). The label needs to clearly indicate the efficacy relates specifically to HIV type 1. In addition, the label needs to clearly indicate the efficacy relates to hard, non-porous surfaces.

Antec Response:

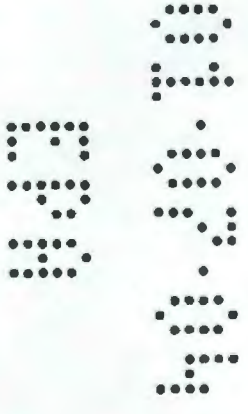
The HIV claim on the proposed label has been modified to make clear it applies to HIV Type 1 on hard non-porous surfaces.

EPA Comment:

The label claims (as supported by MRID No. 41 0574-1 0) <u>are not currently acceptable</u> regarding the use of a 1% solution of the product Virkon S, as a disinfectant against *Escherichia coil, Klebsiella pneumoniae, Staphylococcus epidermidis, Streptococcus pyogenes, Salmonella typhimurium,* and *Candida albicans* in the presence of 400 ppm hard water on hard, non-porous surfaces for a contact time of 10 minutes. Although no growth was observed in subcultures of the carriers tested, the studies were not conducted in the presence of an organic soil load. Page 4 of the label indicates that product "efficacy was determined in the presence of hard water and organic material." To maintain these claims, you must provide information that clarifies whether the 1989 studies or any other studies were conducted in the presence of an organic soil load against the above-listed microorganisms.

Antec Response:

This comment is identical to one above and Antec's response is the same.



*Please read instructions on reverse before completing form.* Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number: 303455

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 62432-1 | Adam Heyward | ☑ None ☐ Restricted |
| **4. Company/Product (Name)** | **PM#** | |
| Virkon S | 34 | |

**5. Name and Address of Applicant** *(Include ZIP Code)*
Antec International Ltd. c/o Delta Analytical Corp.
7910 Woodmont Ave., Suite 1000
Bethesda, MD 20814

☐ *Check if this is a new address*

**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

## Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Proposed amendment responding to your letter of July 22 regarding Reregistration requirements, responding to your letter of August 5 regarding the Spring Viremia of Carp claim, proposing a new basic and several alternate formulas, adding organism claims, and higher dilution rates for specific organisms.

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) |
| *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

NO CHANGES

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☐ Label ☐ Container | | ☐ |

**6. Manner in Which Label is Affixed to Product** ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

## Section - IV

**1. Contact Point** *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Jeff Jones | Agent, Antec International Ltd. | 301 652 5495 |

### Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| 2. Signature | 3. Title | 6. Date Application Received (Stamped) |
|---|---|---|
| Jeff Jones | Agent, Antec International Ltd. | |
| **4. Typed Name** | **5. Date** | |
| Jeff Jones | January 5, 2004 | |



EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

| | |
|---|---|
| Applicant's/Registrant's Name, Address, and Telephone Number<br>Antec International Ltd. c/o Delta Analtical Corporation; 301 652 5495 | EPA Registration Number/File Symbol<br>62432-1 |
| Active Ingredient(s) and/or representative test compound(s)<br>potassium peroxymonosulfate; sodium chloride | Date<br>15 Dec 2003 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)<br>Indoor | Product Name<br>Virkon S |

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

**I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.**

| Signature | Date | Typed or Printed Name and Title |
|---|---|---|
| Jeff Jones | 15 Dec 2003 | Jeff Jones, Agent, Antec International Ltd. |

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M Street, S.W.**
**WASHINGTON, D.C. 20460**

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## DATA MATRIX

| Date 15 Dec 2003 | EPA Reg No./File Symbol 62432-1 | Page 1 of 3 |
|---|---|---|
| Applicant's/Registrant's Name & Address<br>Antec International Ltd. c/o Delta Analytical Corp., 7910 Woodmont Ave., Ste .1000, Bethesda, MD 20814 | Product<br>Virkon S | |

Ingredient potassium peroxymonosulfate; sodium chloride

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830-6302 | Color | see Note 1 | A. H. Robins | PER | 2 |
| 830-6303 | Physical state | -Do- | -Do- | -Do- | -Do- |
| 830-6304 | Odor | -Do- | -Do- | -Do- | -Do- |
| 830-6314 | Oxidation/Reduction | -Do- | -Do- | -Do- | -Do- |
| 830-6315 | Flammability/flame extension | N/A | | | 3 |
| 830-6316 | Explodability | N/A | | | 4 |
| 830-7100 | Viscosity | N/A | | | 5 |
| 830-1650 | Description of formulation process | -Do- | A. H. Robins | -Do- | -Do- |
| 830-1670 | Discussion of formation of impurities | -Do- | -Do- | -Do- | -Do- |
| 830-1800 | Enforcement analytical method | -Do- | -Do- | -Do- | -Do- |
| 830-6317 | Storage stability | -Do- | -Do- | -Do- | -Do- |
| 830-6320 | Corrosion characteristics | -Do- | -Do- | -Do- | -Do- |
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| Signature | Name and Title | Date |
|---|---|---|
| Jeff Jones | Jeff Jones, Agent, Antec International Ltd. | 15 Dec 2003 |

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Ingredient potassium peroxymonsulfate; sodium chloride

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 81-1 | Acute oral toxicity | 41057402 | A. H. Robins | PER | 2 |
| 81-2 | Acute dermal toxicity | 41057403 | -Do- | -Do- | -DO- |
| 81-3 | Acute inhalation toxicity | 41057404 | -Do- | -Do- | -DO- |
| 81-4 | Primary skin irritation | 41057405 | -Do- | -Do- | -DO- |
| 81-4 | Primary skin irritation | 41057406 | -Do- | -Do- | -DO- |
| 81-5 | Primary eye irritation | 41057407 | -Do- | -Do- | -DO- |
| 81-5 | Primary eye irritation | 41057408 | -Do- | -Do- | -DO- |
| 81-6 | Skin sensitization | 41057409 | -Do- | -Do- | -DO- |
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| Signature | Name and Title | Date |
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## DATA MATRIX

| Date 15 Dec 2003 | EPA Reg No./File Symbol 62432-1 | Page 3 of 3 |
|---|---|---|
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Ingredient potassium peroxymonosulfate & sodium chloride

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 91-2 | Product Performance | 41057410 | A.H. Robins | PER | 2 |
| -DO- | -DO- | 41057411 | -DO- | -DO- | -DO- |
| -DO- | -DO- | 41108301 | -DO- | -DO- | -DO- |
| -DO- | -DO- | 41108302 | -DO- | -DO- | -DO- |
| -DO- | -DO- | 41259701 | -DO- | -DO- | -DO- |
| -DO- | -DO- | 41259702 | -DO- | -DO- | -DO- |
| -DO- | -DO- | 45637101 | Antec International Ltd. | own | |
| -DO- | -DO- | to be assigned | Antec International Ltd. | own | 6 |
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| Signature | Name and Title | Date |
|---|---|---|
| | Jeff Jones, Agent, Antec International Ltd. | 15 Dec 2003 |

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DATA MATRIX NOTES
Virkon S (EPA Reg. No. 62432-1)
15 December 2003

1. Neither A.H. Robins or Antec International are able to locate copies of the data previously submitted. Consequently both studies identified as addressing Product Chemistry requirements for the formulation in an NPIRS search are referenced for each data requirement. The MRID numbers for these studies are 42092401 and 41057401.

2. A letter from Timothy T. Slater of A.H. Robins Corporation granting Antec permission to cite this data is attached.

3. Virkon S is manufactured in powdered form. It is neither a combustible liquid or aerosol; flammability is not applicable.

4. Virkon S contains no explosive ingredients. Explodability is not applicable.

5. Virkon S is manufactured in powdered form. Viscosity is not applicable.

6. Multiple product performance studies have been included in the package submitted with this data matrix.

AMERICAN HOME PRODUCTS CORPORATION
FIVE GIRALDA FARMS, MADISON, NEW JERSEY 07940 (973) 660-6535, FAX (973) 660-7176

January 17, 2001

TIMOTHY T. SLATER
ASSOCIATE GENERAL COUNSEL

Ms. Linda S. Propst, Chief
Product Registration Branch, SRRD
Office of Pesticide Programs
US Environmental Protection Agency
Washington DC, 20460

Dear Ms. Propst:

A. H. Robins Company ("Robins") is a subsidiary of American Home Products Corporation and I am counsel to and Assistant Secretary of Robins. In those capacities I am writing on behalf of Robins to grant Antec International Ltd., Chilton Industrial Estate, Sudbury, Suffolk C010 6XD, England permission to cite data listed in Attachment I presently owned by Robins. I understand this data will be cited in support of reregistration of Virkon S (EPA Reg. No. 62432-1) and Virkon (EPA Reg. No. 62432-2).

As the original registrant of Virkon S (EPA Reg. No. 778-91), Robins submitted extensive data in support of its registration. The registration itself was officially transferred to Antec International in 1992. At that time, the intent was to transfer data rights as well, but I understand that has not been formally accomplished. Robins will be submitting the appropriate documents to accomplish that objective shortly.

In the interim, Robins grants Antec permission to cite all Virkon S data presently owned by Robins.

If you have any questions regarding this matter, please contact me.

Very truly yours,

Timothy T. Slater

cc: Jeff Jones, Delta Analytical Corporation

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Ingredient potassium peroxymonosulfate; sodium chloride

| Submitter | Status | Note |
|---|---|---|
| A. H. Robins | PER | 2 |
| -Do- | -Do- | -Do- |
| -Do- | -Do- | -Do- |
| -Do- | -Do- | -Do- |
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| | | 4 |
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| A. H. Robins | -Do- | -Do- |
| -Do- | -Do- | -Do- |
| -Do- | -Do- | -Do- |
| -Do- | -Do- | -Do- |
| -Do- | -Do- | -Do- |
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| Signature | Name and Title | Date |
|---|---|---|
| Jeff Jones | Jeff Jones, Agent, Antec International Ltd. | 15 Dec 2003 |

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| Submitter | Status | Note |
|---|---|---|
| A. H. Robins | PER | 2 |
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| Signature | Name and Title | Date |
|---|---|---|
| JEFF JONES | Jeff Jones, Agent, Antec International Ltd. | 15 Dec 2003 |

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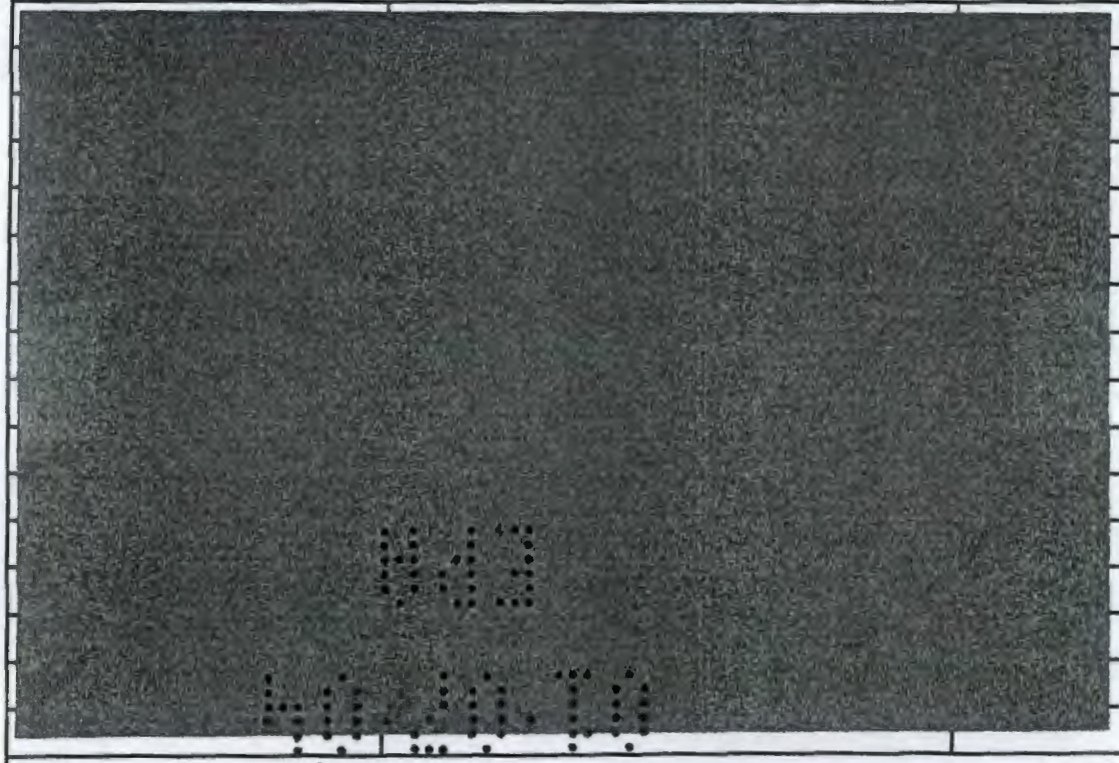
Ingredient potassium peroxymonosulfate & sodium chloride



| Submitter | Status | Note |
|---|---|---|
| A.H. Robins | PER | 2 |
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| Signature | Name and Title | Date |
|---|---|---|
| Jeff Jones | Jeff Jones, Agent, Antec International Ltd. | 15 Dec 2003 |

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DATA MATRIX NOTES
Virkon S (EPA Reg. No. 62432-1)
15 December 2003

1. Neither A.H. Robins or Antec International are able to locate copies of the data previously submitted. Consequently both studies identified as addressing Product Chemistry requirements for the formulation in an NPIRS search are referenced for each data requirement. The MRID numbers for these studies are 42092401 and 41057401.

2. A letter from Timothy T. Slater of A.H. Robins Corporation granting Antec permission to cite this data is attached.

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6. Multiple product performance studies have been included in the package submitted with this data matrix.

AMERICAN HOME PRODUCTS CORPORATION
FIVE GIRALDA FARMS, MADISON, NEW JERSEY 07940 (973) 660-6535, FAX (973) 660-7176

January 17, 2001

TIMOTHY T. SLATER
ASSOCIATE GENERAL COUNSEL

Ms. Linda S. Propst, Chief
Product Registration Branch, SRRD
Office of Pesticide Programs
US Environmental Protection Agency
Washington DC, 20460

Dear Ms. Propst:

A. H. Robins Company ("Robins") is a subsidiary of American Home Products Corporation and I am counsel to and Assistant Secretary of Robins. In those capacities I am writing on behalf of Robins to grant Antec International Ltd., Chilton Industrial Estate, Sudbury, Suffolk C010 6XD, England permission to cite data listed in Attachment I presently owned by Robins. I understand this data will be cited in support of reregistration of Virkon S (EPA Reg. No. 62432-1) and Virkon (EPA Reg. No. 62432-2).

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If you have any questions regarding this matter, please contact me.

Very truly yours,

Timothy T. Slater

cc: Jeff Jones, Delta Analytical Corporation

DELTA
ANALYTICAL
CORPORATION

December 21, 2003

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Efficacy Data Responding to Agency Comments in Letter Dated July 22, 2003**

Dear Adam:

Enclosed please find the following data submitted in response to the Agency's comments in a letter dated July 22, 2003:

- Volume 1 of 1
  AOAC Use-Dilution Method: *Escherichia coli, Klebsiella pneumoniae, Staphylococcus epidermidis, Salmonella typhimurium* and *Streptococcus pyogenes*; Antec Virkon S.
  MRID#

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd.
Enclosures

7910 Woodmont Avenue Suite 300 Bethesda, Maryland 20814
(301) 652-1495 FAX (301) 652 5408

## PM WORK ASSIGNMENT SHEET

**DECISION** _____ **PM** 34

**DESCRIPTION OF ACTION:** _____

**SUBMISSION BAR CODE: S** _____

**PRODUCT REVIEWER:** Bonaventura, A

**FILE SYMBOL/REG NO.:** 62432-1

FQPA ACTION CODE: 307 NON-FQPA ACTION CODE: _____

| AMOUNT OF TIME TO COMPLETE TASK (**ASRC** only) | HOURS_____ |
|---|---|

| | MONTH | DAY | YEAR |
|---|---|---|---|
| APPLICATION DATE | 12 | 21 | 04 03 |
| EPA PIN DATE | 01 | 07 | 04 |
| REVIEWER ASSIGNED DATE | 02 | 02 | 04 |
| DATE DUE OUT OF AGENCY | 02 | 02 | 04 |

**TYPE OF DATA**

**Product Chemistry:** ☐ **Product Toxicology:** ☐ **Efficacy:** ☐

**RASSB:** ☐ **HED TOX** ☐ **ENVIRONMENTAL FATE** ☐ **FISH/WILDLIFE** ☐

**Other** ☐ _____

COMMENTS: Rejection Letter FAXED 2/2/04

COMPLETED

Return to Me (Heyward).

**JACKET(S)/FILE SHOULD BE SUBMITTED WITH YOUR LETTERS FOR SIGNATURE**

RESPONSE CODE: 10 RESPONSE DATE: 02 / 02 / 04
MO Day Year

United States Environmental Protection Agency
Washington, D.C. 20460

Office of Prevention, Pesticides and Toxic Substances
Office of Pesticides Programs
Antimicrobial Division

**FAX NUMBER (703) 308-6466**

**FACSIMILE REQUEST/COVER SHEET**
**(Please type or print clearly in black ink only)**

**SEND FAX TO:**
**Name:** T. Jeffrey Jones, Agent
**Office:** Antec International Ltd, c/o DAC
**FAX phone No.** 301-652-5408
**Office Phone.** 301-652-5495

**FROM:**
**Name:** ADAM HEYWARD
**Division/Branch:** AD/RMB II
**Office Phone No:** 703-308-6422

**Mail Code:** 7510C **Date:** 2-2-04 **Time:** 8:45 AM
**Number of pages (with this cover sheet):** 9

**Special Message:** See attachments

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 23, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DELTA ANALYTICAL CORPORATION
ANTEC INTERNATIONAL LTD
7910 WOODMONT AVENUE, #1000
BETHESDA, MD 20814

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 07-JAN-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [10]:

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submittedstudies) submitted to EPA. This statement must appearas page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Rejected Study [15]:

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and

supplements to previously submittedstudies) submitted to EPA. This statement must appearas page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160 12 for specific guidance.

Rejected Study [16].

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submittedstudies) submitted to EPA. This statement must appearas page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter. and the study director Please see 40 CFR 160 12 for specific guidance.

Rejected Study [17]:

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submittedstudies) submitted to EPA. This statement must appearas page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter. and the study director. Please see 40 CFR 160.12 for specific guidance.

DELTA
ANALYTICAL
CORPORATION

461660-00

January 5, 2004

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

Subject: Virkon S; EPA Reg. No. 62432-1; Your Letters Dated July 22, 2003, and August 5, 2003; New Alternate Formulas; Addition of Organism Claims; Higher Dilution Rates

Dear Adam:

The purpose of this submission is to respond to your letter of July 22 regarding Reregistration requirements, to respond to your letter of August 5 regarding the Spring Viremia of Carp claim, to propose a new basic and several alternate formulas, to add organism claims, and to specify higher dilution rates when specific organisms are targeted. The submission includes:

- Application for Pesticide Registration (EPA Form 8570-1)
- Confidential Statement of Formulas (EPA Form 8570-4; 2 copies)
- Proposed Product Label (5 copies); one copy with proposed changes highlighted
- Current Stamped Label
- Certification with Respect to Citation of Data and Data Matrix (EPA Form 8570-34 and 8570-35)
- Response to Comments in EPA Letter Dated July 22, 2003

The additional required data included in this package are submitted with separate cover letters depending on the purpose of the data submission.

Response to July 22, 2003 Reregistration Letter

In the July 22, 2003, letter following the reregistration review of the Virkon S registration, the Agency requested certain changes in precautionary and first aid statements, and questioned certain organism claims based on previously submitted data. An attachment to this letter, "Response to Comments in EPA Letter Dated July 22, 2003," address each of the Agency's comments in turn. This submission contains requested label changes and in some cases new data addressing organism claim issues.

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814
(301) 652-5495 FAX (301) 652-5408

Spring Viremia of Carp Claim

05-05-04

In your letter of August 5, 2003, you denied the proposed label claim against Spring Viremia of Carp because it is a "public health organism." While I believe the Agency is now convinced it is not a public health organism, I note that it is present on OIE List B. This submission includes the requested efficacy data in the package with data supporting new organism claims.

Replacement Basic Formula

The replacement basic formula corrects the original and current approved formula whose active ingredient percentage was based on the lower certified limit rather than the nominal value. This brings the Virkon S active ingredient percentage for potassium peroxymonosulfate more in line with the Virkon formula (EPA Reg. No. 62432-2). I will be submitting a replacement basic formula for Virkon shortly which is absolutely consistent with the new basic formula for Virkon S. I emphasize that these replacement basic formulas involve no change in the formulation whatsoever, but simply accurately reflect the nominal value for potassium peroxymonosulfate and improved accuracy in the active ingredient percentage calculation.

New Alternate Formulas

The proposed alternate formulas include dye and fragrance-free variations on the basic formula and a new tablet formula. The tablet formula is supported by confirmatory efficacy data which is attached.

New Organism Claims

The proposed label includes new organism claims against *Bacillus cereus, Brucella abortus, Campylobacter jejuni, Chlamydia psittaci, Listeria monocytogenes, Shigella sonnei,* Spring Viremia of Carp Virus, Swine Vesicular Disease Virus, and Trichophyton mentagrophytes. Data supporting these claims is submitted herein. The data on Swine Vesicular Disease is included in the data package for higher dilution rates discussed below.

A new animal health claim against Mouse Parvovirus and a new plant pathogen claim against *Xanthomonas axonopodis* are also proposed in this submission. Supporting efficacy data for these claims has not been submitted but is available for submission.

Higher Dilution Rates

The proposed label includes a new use pattern titled "Disinfection Limited to Specific and Known Disease Organisms." For general disinfection, the recommended application

rate calls for a 1% solution. When Virkon S is used for a specific and known disease outbreak, Antec would like to recommend higher dilutions (weaker solutions). Data evaluating Virkon S efficacy at the proposed dilution rates are included in this submission.

If you have questions about this submission or need additional documents or clarification, please contact me.

Thanks for your assistance.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd.

Enclosures

DELTA
ANALYTICAL
CORPORATION

·05·04

EPA

December 21, 2003

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Efficacy Data Responding to Agency Comments in Letter Dated July 22, 2003**

Dear Adam:

Enclosed please find the following data submitted in response to the Agency's comments in a letter dated July 22, 2003:

- Volume 1 of 1
  AOAC Use-Dilution Method: *Escherichia coli, Klebsiella pneumoniae, Staphylococcus epidermidis, Salmonella typhimurium* and *Streptococcus pyogenes*; Antec Virkon S.
  MRID# 46166001

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd.
Enclosures

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814
(301) 652-5495 FAX (301) 652-5408

DELTA
ANALYTICAL
CORPORATION

05-04

EPA

December 21, 2003

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Confirmatory Efficacy Data Submission for Tablet Formulation**

Dear Adam:

Enclosed please find the following data submitted to support new tablet formuation:

- Volume 1 of 2
  Product Chemistry: Supplement to Manufacturing Process Description; Virkon S Tablets
  MRID# 46166002

- Volume 2 of 2
  AOAC Use-Dilution Method: *Staphylococcus aureus* (ATCC 6538) and *Salmonella cholerasuis* (ATCC 10708).
  MRID# 46166003

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,

Jeff Jones

T. Jeffrey Jones, Agent
Antec International Ltd.
Enclosures

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814
(301) 652-5495 FAX (301) 652-5408

DELTA
ANALYTICAL
CORPORATION

05-04

EPA

December 21, 2003

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Data Submission to Support New Organism Claims**

Dear Adam:

Enclosed please find the following data submitted in support of new organism claims on the Virkon S label:

- Volume 1 of 8
  The Evaluation of the Efficacy of Virkon S against *Campylobacter jejuni* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load
  MRID# 46166004

- Volume 2 of 8
  The Evaluation of the Efficacy of Virkon S against *Brucella abortus* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load
  MRID# 46166005

- Volume 3 of 8
  10 Minute Inactivation of *Chlamydia psittaci* by Virkon S
  MRID# 46166006

- Volume 4 of 8
  AOAC Use-Dilution Method: *Listeria monocytogenes* (ATCC 19117)
  MRID# 46166007

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- Volume 5 of 8
  The Evaluation of the Efficacy of Virkon S against *Pseudomonas aeruginosa* and *Bacillus cereus* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load
  MRID# 46166008

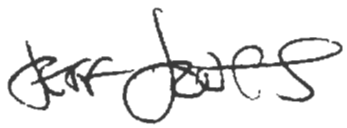
- Volume 6 of 8
  The Evaluation of the Efficacy of Virkon S against *Shigella sonnei* in the Presence of AOAC Synthetic Hard Water and a 5% Soil Load
  MRID# 46166009

- Volume 7 of 8
  Efficacy of Virkon-S against SVCV
  MRID# Reject (10)

- Volume 8 of 8
  The Evaluation of the Efficacy of Virkon S against *Tricophyton mentagrophytes* in the Presence of Hard Water and a 5% Soil Load
  MRID# 46166011

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,



T. Jeffrey Jones, Agent
Antec International Ltd.
Enclosures

DELTA
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CORPORATION

December 21, 2003

Mr. Adam Heyward, PM #34
Antimicrobials Branch
US EPA
Washington, DC 20460

**re: Virkon S; EPA Reg. No. 62432-1; Efficacy Data to Support Higher Dilution Rates**

Dear Adam:

Enclosed please find the following data submitted to support the higher dilution rates (weaker solutions) on the Virkon S directions for use:

- Volume 1 of 8
  Ministry of Agriculture, Fisheries and Food: Approval of Disinfectants-Antec Virkon S
  MRID# 46166012

  [This study was previously reviewed in conjunction with the Agency's approval of the Foot and Mouth Disease claim several years ago.]

- Volume 2 of 8
  Laboratory Evaluation of Antec Virkon S Disinfectant as a Virucidal Agent against Infectious Bursal Disease (Gumboro) Virus
  MRID# 46166013

- Volume 3 of 8
  The Virucidal Effect of Virkon S on Chicken Anaemia Agent
  MRID# 46166014

- Volume 4 of 8
  Virucidal Effectiveness Test
  MRID# Reject (15)

7910 Woodmont Avenue Suite 1000 Bethesda, Maryland 20814
(301) 652-5495 FAX (301) 652-5408

- Volume 5 of 8
  The Determination of Efficacy of Virkon S at Two Dilutions against Three Isolates of *Mycoplasma mycoides subspecies mycoides* small colony type using the Hard Surface Carrier Test Method and in Use Test Method
  MRID# Reject (16)

- Volume 6 of 8
  Test for Efficacy (Virkon S) against African Swine Fever
  MRID# Reject (17)

- Volume 7 of 8
  Laboratory Evaluation of Antec 'Virkon S' Disinfectant as a Virucidal Agent against Avian Influenza Virus
  MRID# 46166018

- Volume 8 of 8
  Virucidal Effectiveness Test; Porcine circovirus; Test Agent: Virkon S
  MRID# 46166019

If you have any questions regarding this submission, please contact me as soon as possible.

Sincerely,

T. Jeffrey Jones, Agent
Antec International Ltd.
Enclosures

Pages 259-274 - *Confidential Statements of Formula may be entitled to confidential treatment*

## CERTIFICATION STATEMENT

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of **Virkon S,** EPA Reg No. 62432-1 refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that:

1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit specified for that ingredient in a currently approved Statement of Formula; and

2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

Company: Antec International Ltd.

Company Agent: T. Jeffrey Jones

Signature: Jeff Jones

Date: March 22, 2001

Pages 276-277 - *Confidential Statements of Formula may be entitled to confidential treatment*

**Virkon S**

**EPA Reg. No. 71654-6**

Certification Statement

for

Confidential Statement of Formula

I hereby certify that, for purpose of FIFRA sec. 12(a)(1)(c), the description of the composition of Virkon S, EPA Reg. No. 71654-6, refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

D. Stockford

Dean Stockford
Plant Manager
DuPont Animal Health Solutions
Sudbury, Suffolk, UK

March 4. 2005

Date

Pages 279-297 - *Confidential Statements of Formula may be entitled to confidential treatment*

## CERTIFICATION STATEMENT

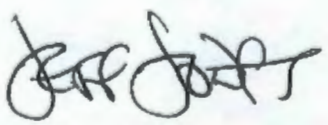
I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of **Virkon S,** refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that:

1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit specified for that ingredient in a currently approved Statement of Formula; and

2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

Company: Antec International, Ltd

Company Agent: T. Jeffrey Jones

Signature: 

Date: January 5, 2004

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 27, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MS. NANCY B. LOMAX
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE DIVISION
BMP 23/2161, PO Box 80023
WILMINGTON, DE 19880

Dear Ms. Lomax:

Subject: Transfer of Pesticide Registrations and Data From Company Number 62432 to Company Number 71654

Pursuant to your request in your letter and transfer agreement of August 24, 2004, we have approved the transfer of the following registrations and data from ANTEC INTERNATIONAL LTD, company number 62432 to E.I. DUPONT DE NEMOURS AND COMPANY, company number 71654.

The effective date of these changes is the date of this letter.

| Registered Products | Old EPA Reg. No. | New EPA Reg. No. |
|---|---|---|
| VIRKON S | 62432-1 | 71654-6 |
| VIRKON | 62432-2 | 71654-7 |

| Pending Registered Products | Old EPA File Symbol | New EPA File Symbol |
|---|---|---|
| HYPEROX | 62432-G | 71654-I |

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or

package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated August 24, 2004 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date E.I. DUPONT DE NEMOURS AND COMPANY will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Donna G. Parker
Information Management Specialist
Information Services Branch
Information Resources & Services Div. (7504C)

cc: MR. T. JEFFREY JONES
DELTA ANALYTICAL CORPORATION, AGENT FOR
ANTEC INTERNATIONAL LTD
7910 WOODMONT AVENUE, #1000
BETHESDA, MD 20814